IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	: HON. DAN A. POLSTER
APPLIES TO ALL CASES	: NO. 1:17-MD-2804

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

JANUARY 22, 2019

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Videotaped sworn deposition of BRIAN LORTIE, taken pursuant to notice, was held at McCARTER & ENGLISH, LLP, 1600 Market Street, Suite 3900, Philadelphia, Pennsylvania, beginning at 9:06 a.m., on the above date, before Margaret M. Reihl, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Bill Geigert, I am a videographer for Golkow Litigation Services. Today's date is January 22nd, 2019, and the time is 9:06 a.m. This video deposition is being held in Philadelphia, Pennsylvania in the matter of National Prescription Opiate Litigation for the U.S. District Court, Northern District of Ohio, Eastern Division.

The deponent is Brian Lortie.

Counsel will be noted on the stenographic record.

The court reporter is Peg Reihl and she will now swear in the witness.

... BRIAN LORTIE, having been duly sworn as a witness, was examined and testified as follows:

BY MS. SCULLION:

Q. Good morning, Mr. Lortie.

A. Good morning.

Q. We met briefly off the record, but for the record, my name is Jennifer

Scullion, and I represent the plaintiffs in this matter.

Mr. Lortie, I'm going to hand you what's been marked as Exhibits 1 and 2.

(Documents marked for identification as Endo-Lortie Deposition Exhibit Nos. 1 and 2.)

BY MS. SCULLION:

Q. Let me hand you Exhibit 1, which is a copy of the Notice of Deposition of Brian Lortie.

A. Thank you.

Q. And Exhibit 2 which is a copy of the subpoena.

Mr. Lortie, before we look at the exhibits, have you ever been deposed before?

A. Yes, I have.

Q. How many times?

A. I would have to think, but it's been several, probably five or six.

Q. Were all of those in connection with your employment with Endo?

A. The majority have been yes, some -- one or two with my prior employer.

Q. And starting with the depositions for Endo, can you tell me the subject matter of the lawsuits that the depositions took place in?

A. Sure. To the best of my recollection, they were either patent litigation or there were two actual anti-trust cases, and that's, I think, a complete record.

Q. My understanding is you did testify before in an FTC proceeding. That was an in court proceeding, right?

A. Correct, yes.

Q. Did you also testify in deposition, or are you counting that as one of the depositions I asked you about?

A. I'm counting that as one of the depositions in front of the FTC, yes, yes.

Q. Okay. All right. And that was -- that was the Impax matter, correct?

A. The FTC was involved in Impax and I think it also involved Lidoderm as well, if I'm recalling correctly.

Q. All right. Other than patent litigations and anti-trust litigations, did you testify in any other proceedings when you were

with Endo?

A. No, I believe that's complete.

Q. Did you testify before the New York Attorney General?

A. No, I did not.

Q. Did you submit written testimony or declaration?

A. I don't recall. I may have. I'm not sure.

Q. All right. And you said that other than testimony with respect to your work with Endo, you also testified for some prior employers. Can you tell me about those?

A. Sure. GlaxoSmithKline was my prior employer for the majority of my career. There were two, I believe, depositions. One was a patent case, intellectual property case, and then quite a bit earlier I was a witness in an employee relations age discrimination case, again, with regards to my employment there. I wasn't involved in the case. I was a deponent.

Q. So you've testified a number of times, so I'm sure you're quite familiar with the process, and counsel has, I'm sure, prepared

you well, but just so we can go over a couple of ground rules for today.

Probably most important is that we try to not speak over each other because Peg, our court reporter, needs to be able to take down our words, so I'm going to try to not speak over your answers, if you could wait until I finish my questions, and that way we can keep it straight for the court reporter.

Does that work for you?

A. Sure. I will do my best.

Q. Thanks. The other thing is, again, for the court reporter, we do need to have actually oral responses, not shaking head or uh-huh or uh-uhs. We need to actually put words on the piece of paper.

Does that work for you?

A. Yes, I understand.

Q. Okay, great. And then if at any point today you don't understand one of my questions, would you please let me know?

A. Yes, I will.

Q. Thank you. Is there any reason that you can't give your best testimony today?

A. No, I don't think so.

Q. Not taking any medication that would affect your cognitive abilities, for example?

A. That's correct.

Q. That's correct that you're not taking any?

A. It's correct I am not.

Q. Okay, thank you very much.

If you'll look at Exhibit Number 1, this is the Notice of Deposition of Brian Lortie.

Are you aware that you are here today to testify as a representative for Endo on certain topics?

A. I am, yes.

Q. And are you aware you're also here to testify today in your personal capacity?

A. Yes.

Q. Are you represented by counsel today?

A. I am.

Q. Who is that?

A. Counsel to my left from Goodell,

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as well as Carrie Hazard from Endo.
Q. Okay. And can you just briefly go over what I understand to be the topics that you are to be representative on today, and I'll ask you let me know if you understand these to be the topics as well.
So the first topic --
MR. LIMBACHER: Jen, I don't mean to interrupt.
MS. SCULLION: No, please.
MR. LIMBACHER: Just for purposes of the record, I think Endo has served objections to the 30(b)(6) notice, and I think there's also been considerable correspondence back and forth between counsel with regard to the scope of the topics on which he has been designated. So if there's any issues or concerns there, I'm happy to discuss it with you, but I think you know the basic scope on which he is being presented as a 30(b)(6) witness.
MS. SCULLION: And I'd just like to confirm it with the witness. I agree

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with those statements.
BY MS. SCULLION:
Q. So the first topic is any analysis of the effectiveness of Endo's sales or marketing efforts, including any analysis of return on investment in sales or marketing activities related to Endo's opioid products.
Do you have an understanding that you're testifying on those topics?
A. Yes. Is that -- I mean, I see that the topics are listed by number here. Can I also take a look at the subpoena, just so I'm --
Q. The subpoena is actually different, and we will get to that. The subpoena is directed to you in your personal capacity.
A. Okay.
Q. And we will get to that.
What I just recited was identified as topic number 9, and you said, yes, you understand you're going to be testifying on that topic?
A. Yes, I was just accustomed to

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seeing it in writing, so but, yes, that sounds like number 9.
Q. And the next topic, which is topic number 13, is the process for determining the accuracy, completeness and legality of and approval and implementation of any sales or marketing information Endo made available to medical professionals, patients or the public concerning opioids or any of Endo's opioid products in any format, including printed materials, videos, websites, any in-person messaging or detailing by sales representatives.

Do you understand that you're going to be testifying as to that process, generally?
A. Yes, yes.
MR. LIMBACHER: Jen, just so we're clear on the record, he'll be testifying consistent with and subject to the objections that Endo has served you with with regard to the 30(b)(6) notice and also within the scope of what we have identified as appropriate areas

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for testimony with regard to each of these topics, and that's been set forth in considerable e-mail between I believe yourself and Josh Davis.
MS. SCULLION: And you'll let me know, obviously, you'll make an objection if you think it's outside the scope.
BY MS. SCULLION:
Q. With respect, though, to the claims in marketing information concerning Endo's opioid products, do you also understand that you are prepared to testify to certain specific claims that we provided to counsel to testify to just what was the support for those claims?
A. Yes, I understand that.
Q. Okay. And we have a chart that we've been provided with, and we can walk through some of that.
The next two topics that are quite similar, and they relate to the applicable policies, procedures, records and systems for abuse and diversion issues at Endo. And on that

what we've agreed to is that you be prepared to testify to the substance of the reasons for any changes to those policies or procedures, the effectiveness of those policies or procedures.

And then topic 32 also goes to the procedures, record systems, training policies for ensuring compliance with abuse and diversion laws and regulations and, again, the substance of any reasons for any changes to those and the effectiveness of compliance procedures.

Do you understand you're testifying to those issues as well?

MR. LIMBACHER: Let me just object, because I don't know that you accurately characterized Endo's position with regard to what he's actually going to be designated to testify on with regard to topics 30, 31 and 32. The general subject matter you have accurately described, but in terms of the specifics of what he's prepared to testify to, I believe you misstated, but having said that, you can answer the

question, as best you can.

MS. SCULLION: Well, on that we probably should then take a break, because I'm reading from language from an e-mail I sent to Josh Davis and that he confirmed. So I do want to be sure that we are on the same page on that. So let's finish this, and then, I think, take a quick break because I do want to make sure that we're on the same page.

BY MS. SCULLION:

Q. You also would speak to the role of wholesalers, distributors and pharmacies in monitoring for abuse and diversion?

A. Yes.

MR. LIMBACHER: Topic 31.

MS. SCULLION: Thirty-one, yes.

THE WITNESS: Yes. And I believe there's a call out one exception to that, where another witness has been designated as corporate representative for one of the topics or one of the subtopics.

BY MS. SCULLION:

Q. Right. Is it your understanding that a separate representative will be speaking to suspicious order monitoring procedures?

A. Yes, that's my understanding.

Q. Okay. That's my understanding as well, so good.

And then topic 39 is any effort you made directly or through any third party to collaborate with one or more other pharmaceutical manufacturers or distributors concerning marketing, use, prescribing, sale, distribution or regulation of any one or the class of opioid products, including any collaborative lobbying efforts concerning any of the foregoing.

And do you understand you're prepared to testify to that topic as well?

A. I do.

MS. SCULLION: Why don't we take a short break, because I do want to clarify off the record on topics 30 and 32. I apologize.

THE VIDEOGRAPHER: Off the record, 9:18 a.m.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record at 9:37 a.m.

MS. SCULLION: So we went off the record and had a discussion with Mr. Limbacher, and, Mr. Limbacher, will you confirm that my description of the topics for Mr. Lortie in 30 and 32 -- 30, 31 and 32 are accurate?

MR. LIMBACHER: I believe that is consistent with the e-mail exchanges between Mr. Davis and yourself, but we stand by whatever is in those e-mails and, also, our objections to the 30(b)(6) notice.

MS. SCULLION: Okay. And it's our understanding that the objections have been addressed through the e-mail exchange. We won't burden the record further on that.

BY MS. SCULLION:

Q. Mr. Lortie, can you look at Exhibit Number 2, which is the subpoena?

A. Yes.

Q. Have you seen the subpoena before?
A. Yes, I have.
Q. And do you understand it was directed to you personally?
A. I do, yes.
Q. Okay. And the subpoena, if you will turn to page 2, has categories of documents that were requested.
Did you search your personal records for these documents?
A. I don't have any personal records with regards to this, but I was asked to confirm that, yes.
Q. Okay. And that includes looking, for example, at personal e-mails?
A. Correct.
Q. Okay. Terrific. We can put aside Exhibit.
Number 2.
This morning we were handed a copy of your CV.
Let me hand you a copy that's been marked Exhibit Number 3.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 3.)
BY MS. SCULLION:
Q. Do you recognize Exhibit Number 3?
A. I do.
Q. And what is it?
A. It's a current copy of my resume.
Q. This is a resume you prepared?
A. It is.
Q. And, to the best of your knowledge, it's accurate?
A. Yes.
Q. Okay. We can go back, start at the beginning. As we were discussing off the record, you have an undergraduate degree from BU and that's a pre-med degree, correct?
A. It is correct, yes.
Q. And then you went on to Villanova for business school?
A. I did, yes.
Q. And in terms of your employment history, looks like the entirety of your career

has been spent in the pharmaceutical industry, correct?
A. That is correct.
Q. And you started off at SmithKline in 1987, and, as I read your resume, you joined Endo in July of 2009; is that correct?
A. It's actually 1986.
Q. I'm so sorry.
A. Just to correct the record, when I began with SmithKline, but you're correct, 2009 was when I joined Endo.
Q. Okay. And before joining Endo, had you had any experience with marketing or sales of controlled substances?
A. No.
Q. Did any of your prior -- any of your work before Endo concern any pain products?
A. No, it did not.
Q. And at Endo, so you began in July of 2009 as senior vice president and general manager for branded pharmaceuticals.
And then you were promoted to president for US branded pharmaceuticals in May of 2014, correct?

A. That's correct.
Q. And then you were promoted again to president and CEO -- I'm sorry, I got that wrong entirely -- and then you left Endo in October 2016, correct?
A. That is correct, yes.
Q. All right. Before we go back into that, can we have Exhibit Number 4.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 4.)
BY MS. SCULLION:
Q. Hand you Exhibit Number 4 Bates stamped ENDO_OPIOID_MDL_DEPONENT-000019346.
Do you recognize Exhibit Number 4?
A. Yes, I do.
Q. And what is it?
A. This is the Separation Agreement from Endo in 2016.
Q. Why did you leave Endo in 2016?
A. It was as an agreement between myself and the executive team and the board, I had indicated that at a certain time I wanted to

move on and do a different part of the pharmaceutical industry, which I subsequently have done. The board asked me to remain for a period of time until a successor had been recruited and brought on board, which I agreed to do. So this memorialized the terms of that agreement.

Q. Make sure I understand, looking at Exhibit 4, it's dated June 27th, 2016, and you list on your CV that you left Endo in October of 2016.

Do I understand correctly that you entered into an agreement in June of 2016 where you would stay on for a short period of time while Endo tried to find a successor?

A. And specifically this, the agreement was entered into in May. The signature is dated in June, but from May until I left in October, that was the period where I had agreed to stay in my role until I could do a hand-off to a successor.

Q. Had you been asked to leave?

A. Not specifically, no.

Q. When you say "not specifically,"

had there been indications that Endo would prefer that you leave?

MR. LIMBACHER: Object to form.

THE WITNESS: No. It was an agreement that it was -- between the parties, between the two of us of the terms of the agreement, the time of the agreement, what I would do until the time came that I left.

BY MS. SCULLION:

Q. Was there any particular circumstance that led you to come to an agreement with Endo in May that contemplated you would be leaving, anything at all, any discussions other than your personal --

MR. LIMBACHER: Object to form, asked and answered.

THE WITNESS: No. No, it was the timing that I wanted to do that. I wanted to move on to do something different in my career, and that would be engaged in the founding of a company involving drug development, which I ended up doing, and it was time for me

to do that.

BY MS. SCULLION:

Q. Okay. And looking at Exhibit 4, the Separation Agreement, looking at paragraph 3, which is "Remuneration Upon Termination," on to the carryover page 2, subsection (i), do I understand correctly that as part of the Separation Agreement, you received a payment of [redacted]

A. Yes, I did.

Q. What was the approximate amount of that payment?

A. [redacted]

Q. And it says base salary and target bonus.

So with the target bonus, what was the total amount?

A. If I remember correctly, my target bonus was [redacted] at target. So, again, doing the math on that, that probably adds another [redacted] I'm sorry, I'm not going to do the math in my head, but in that general

area.

Q. So the payment to you by Endo under this agreement was sounds like roughly about [redacted]?

A. Thereabouts. There was also some payment for unused vacation time, et cetera, but I think that's in the range, yes.

Q. Okay. And then if you'll go down to paragraph number 6, "Nondisparagement and Cooperation," under that subparagraph (a) "Nondisparagement," you agreed not to disparage or encourage or induce others to disparage Endo, et cetera.

Does that nondisparagement clause apply today to your testimony?

MR. LIMBACHER: Object to form.

THE WITNESS: I believe it does. It's important also to point out that that does not limit my accurate testimony under oath, which, of course, I understand I'm under oath, and that's -- that's described in the paragraph as well.

BY MS. SCULLION:

Q. And then the next paragraph for "Cooperation," paragraph (b) on page 3, are you serving as Endo's corporate representative pursuant to the cooperation provision here?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not really sure I understand the question, but perhaps if I can --

BY MS. SCULLION:

Q. Let me ask it more cleanly.

A. Sure.

Q. Sure. You're no longer employed by Endo, right?

A. That's correct.

Q. Why did you agree to be Endo's corporate representative today?

MR. LIMBACHER: Object to form.

THE WITNESS: I have no objections to doing so. I have knowledge that could be helpful in the case, so I agreed to do that.

BY MS. SCULLION:

Q. Okay. And are you being paid for your time in connection with today's deposition?

MR. LIMBACHER: Object to form.

THE WITNESS: I am.

BY MS. SCULLION:

Q. And if you look at paragraph (c) under -- subparagraph (c) under paragraph 6 it states a rate of $250 per hour for cooperation.

Are you being paid that rate?

A. Yes, I am.

Q. Were you paid for time spent preparing for the deposition?

A. Yes, at the same rate.

Q. Okay. And you're being paid for your time actually testifying today as well?

MR. LIMBACHER: Object to form.

THE WITNESS: Correct. I'm being paid for my time in general.

BY MS. SCULLION:

Q. Okay. Other than preparing for today's deposition and being here today as Endo's corporate representative on certain topics, have you provided any other cooperation to Endo in connection with this litigation?

MR. LIMBACHER: Object to form.

I'd caution the witness not to inadvertently disclose any privileged communications, but you can go ahead and answer the question.

THE WITNESS: No. All of my work done has been in preparation for this deposition with regards to this litigation.

BY MS. SCULLION:

Q. And to make sure just more broadly, since leaving Endo, have you been paid for your time by Endo in connection with anything other than this litigation?

A. Only other litigation, which we described before, other depositions in the same fashion.

Q. Okay. Do you have any -- other than the Separation Agreement, which is Exhibit 4, do you have any other current agreements with Endo?

A. I do not.

Q. Do you have any current financial interest in Endo?

A. I still remain a shareholder, so

I own some equity, but, other than that, no.

Q. Do you know today approximately how many shares you hold?

A. I may hold -- it's difficult to give an accurate number, but probably, to my best estimate, maybe [redacted] shares.

Q. Do you have any options currently?

A. I have no active options, no.

Q. Okay. And just to be -- make sure, I've asked a series of questions about your relationships with Endo, do you have any current relationship with Par, Par Pharmaceuticals?

A. Not -- no.

Q. And do you have any -- so no current agreements, correct?

A. That's correct.

Q. And no current financial relationship with Par?

A. That's correct.

Q. Okay. Let's go back to your CV, Exhibit Number 3, and focusing on your time at Endo. It says here that you were -- on page 2

that you were a member of the executive leadership team.

What was that?

A. Yes, and, again, I should point out just for accuracy, that period described 2009 through 2014, my job responsibilities evolved over time, more things were added and at the -- I would say around the middle of 2013, I was named to the executive leadership team. The executive leadership team was essentially the senior leaders of the corporation, for the most part, direct reports of the CEO. And there were periods of time there where I was a direct report. There were also some periods of time there where there was a chief operating officer that I reported to and that person reported to the CEO.

Q. Do you know which period of time you reported to a chief operating officer?

A. The first chief operating officer I reported to in, if I recall correctly, March of 2011, and I believe she left in May of 2013. From May of 2013, if my recollection is correct, until around August or September of 2013, I

reported to the chief executive.

Then another chief operating officer was recruited and I reported to him until sometime in 2014, when he departed. I don't recall the exact date.

And from that point forward until the end of my employment with Endo, I reported directly to the chief executive.

Q. Okay. What were the responsibilities of the executive leadership team?

A. They -- the executive leadership team was responsible for the management of the operations, strategy of the company. So, again, it was the senior leaders that represented all of the corporate functions and direct reports, as I said, with a few exceptions to the chief executive.

Q. Did the executive leadership team while you served on it have any responsibilities with respect to any of Endo's generic products?

A. There -- those responsible for the generic business division, which was a distinct separate division from the branded

division, were represented on that, and, of course, by virtue of the role of the chief executive, he was also responsible for that business.

I should also say that there would have been members of the executive leadership team in some of the corporate functions that also supported all of the businesses. I'm thinking legal and human resources and finance, for example.

Q. During the time that you were employed by Endo, I want to make sure I understand, were you ever a member of the PMRB?

A. I was not a direct member of the PRB, although those who were reporting to me or reporting up through my business were sitting members on that team.

Q. But you, yourself were not a member of the PMRB?

A. I believe I was not directly myself.

Q. And we'll talk a little bit in more detail about PMRB in a bit, but, similarly, you, yourself, were not a member of MARC,

correct?

A. Correct, same answer with regards to MARC. MARC was really an evolution of PMRB.

Q. Did you ever sit on the risk management committee?

A. The risk management committee I did not. That was members cross-functionally of medical, legal, regulatory, and I believe risk management had marketing representation, and those people would have also reported up, but I didn't sit specifically on that, no.

Q. Okay. There's reference also to the Endo -- I think Endo Safety Review Board, ESRB. Were you ever a member of the ESRB?

A. No, that had membership, if my recollection is correct, similar to the risk management committee but with the exception of having no commercial representation, so risk -- I mean safety review board was just medical, primarily medical and legal and perhaps regulatory.

Q. Okay. Did you ever sit on any compliance committee at Endo?

MR. LIMBACHER: Object to form.

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THE WITNESS: I'm -- I don't recall specifically. Of course, I was well involved with our compliance officer and familiar with the activities and the requirements of that, but whether or not I actually sat on a compliance committee, sitting here today, I don't recall.

BY MS. SCULLION:

Q. And you recall that Endo did enter into a corporate integrity agreement following the Lidoderm investigation, correct?

A. Yes, that's correct.

Q. And you were a certifier under that corporate integrity agreement; is that right?

A. Yes, I was.

Q. This is probably an important point of clarification in terms of the scope of your testimony as a corporate representative today, we've been speaking of Endo. There was a period of time when Qualitest was a subsidiary of Endo, correct?

A. Yes.

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Q. And are you going to be speaking today about the policies and procedures at Qualitest with respect to abuse and diversion issues?

MR. LIMBACHER: Object to form.

THE WITNESS: I am most familiar and prepared extensively on those that pertain to the branded business, which was my area of responsibility, and the company involved Qualitest was actually the result of an acquisition, and there were some distinctions there and some -- frankly some personnel that we were able to take advantage of, but I'm not specifically prepared to testify in depth to Qualitest's policies and procedures.

BY MS. SCULLION:

Q. Okay. And the Qualitest functions were eventually moved over to Par after the Par acquisition, correct?

A. Yes, that's correct. Qualitest was a generic business, and so either as a stand-alone or when Par came in as an extension

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or expansion of our generic business, they were put together.

Q. Okay.

MS. SCULLION: Can I have the open letter.

MR. LIMBACHER: Jen, I assume we're going to handle this one the way we handled Kristin Vitanza's deposition. You will let us know on the record when you're going to be asking him questions in his capacity as a 30(b)(6) witness, and then when you finish those questions, you'll let us know that you've finished and to the extent there's any uncertainty, we will assume that he is being questioned in his capacity as a fact witness.

MS. SCULLION: Yes.

MR. LIMBACHER: Thank you.

MS. SCULLION: Thank you.

BY MS. SCULLION:

Q. And if you ever have any questions during the day about what capacity I'm asking you questions in, please, again, just let

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me know.

A. I will ask for clarification. Thank you.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 5.)

BY MS. SCULLION:

Q. Let me hand you a copy what's marked as Exhibit Number 5, which is a document taken from Endo's website entailed "Endo's Open Letter on the Opioid Abuse Crisis."

And, Mr. Lortie, if I can direct your attention to the second paragraph, which discusses, The US FDA has worked to balance access to pain care medications for appropriate patients while aggressively mitigating the risks of opioid abuse.

And the next sentence "Endo supports these efforts and has taken parallel actions."

Let me ask you this question: As Endo's corporate representative, are you familiar with the actions that Endo has taken, the parallel actions Endo has taken to mitigate

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the risks of opioid abuse?
MR. LIMBACHER: Object to form. Take your time and review the document.
THE WITNESS: Yeah, I just -- this letter actually, I believe, came out after I left the company, but if I could just take a second just to read it for context.
MS. SCULLION: Yes, please.
THE WITNESS: Thank you.
MR. LIMBACHER: And you're questioning him with regard to which topic?
MS. SCULLION: I believe this would be topic at least 30, likely 32. Again, I think those two bleed together.
(Witness reviews document.)
THE WITNESS: Okay, thank you. I've had a chance to look it over.
BY MS. SCULLION:
Q. Terrific.
MR. LIMBACHER: Sorry, Jen. Just note my objection to the extent the exhibit that you're questioning him

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about I think goes beyond the scope of topics 30 and 32, but you can go ahead and ask your questions.
MS. SCULLION: Well, we really do need to understand that, because this does speak to parallel actions to mitigate the risks of opioid abuse, and topic 30 does speak to policies and procedures to, among other things, halt abuse. So our understanding is this falls squarely within the scope of the topic.
MR. LIMBACHER: It also goes on to talk about things like, for example, the voluntary withdrawal of Opana ER from the market, which I think is beyond the scope of the topics and also is beyond the time period in which he was an employee at the company.
MS. SCULLION: I mean, to the extent that Endo has identified these actions as being actions to mitigate the risks of opioid abuse, again, I think they fall squarely within the topic, and

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I understand he was not at the company, but he is here today as the corporate representative on those issues, but let me just ask you.
BY MS. SCULLION:
Q. Are you prepared today to testify as Endo's corporate representative with respect to the -- what's described here some of -- as the parallel actions Endo took to mitigate the risks of opioid abuse?
MR. LIMBACHER: Well, he's prepared to testify consistent with the e-mail exchanges between counsel and subject to the objections to the 30(b)(6) notice.
BY MS. SCULLION:
Q. Let me ask you, as Endo's corporate representative, did Endo voluntarily stop promoting opioid products to healthcare professionals as one aspect of mitigating of the risks of opioid abuse?
MR. LIMBACHER: I'm going to object to that question as being beyond the scope of the topics on which he has

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been designated and as agreed upon between counsel in e-mails, but he can go ahead and answer the question.
THE WITNESS: That action took place after I had departed the company, although there were periods of time while I was responsible for that business where we had dramatically reduced promotion of our opioid products or, in fact, in certain periods of time eliminated active promotion. But I do believe, as I read this, specific cessation of that activity that's referred to in this letter did take place after I had departed.
BY MS. SCULLION:
Q. So if I understand, you're not prepared to testify today as Endo's corporate representative to that particular action identified as an action Endo took to mitigate the risks of opioid abuse?
MR. LIMBACHER: Again, I'm going to object to the question to the extent it's beyond the scope of the topics on

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which he's been designated, but you can go ahead and answer the question.

THE WITNESS: I've prepared to discuss the many things that Endo had in place, not just from September 2016 onward but really back even predating my arrival and able to discuss those things in detail. Endo has always been committed to taking whatever steps it could to mitigate abuse, diversion, improper prescribing, et cetera.

But to the specifics around the decision to be permanently -- to permanently stop promoting Opana ER as referred to here, there's a limit to which I can represent anything there because it happened after I had departed.

MS. SCULLION: I think we'll get back to the preparation for being a corporate rep, but just to make sure I understand the lines being drawn here, counsel, is it your position that steps Endo took to mitigate the risks of

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opioid abuse are beyond the scope of the topics here.

MR. LIMBACHER: No. My position is that he's prepared to testify consistent with the e-mail exchanges that you entered into with Mr. Davis. He's here to testify with regard to the policies regarding diversion, and I think that questions with regard to the voluntary withdrawal, which postdate his employment at the company, are outside the scope of the topics on which he has been designated.

MS. SCULLION: I apologize for burdening the record, but are you saying he is designated solely with respect to the issue of diversion, because our understanding is he was designated with respect to both diversion and abuse?

MR. LIMBACHER: He's -- yes, he's here to testify with regard to diversion and abuse with regard to topic number 30, I believe.

MS. SCULLION: Correct. And so

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steps that Endo took to mitigate abuse, how do those not fall squarely within the scope of the topic?

MR. LIMBACHER: How does what? I'm confused by what your question is of me at this point in time.

MS. SCULLION: The question is why he would not be prepared to speak to -- as a corporate representative to speak to Endo's actions taken to mitigate the risks of opioid abuse.

MR. LIMBACHER: He is prepared to testify about that. The point I've been trying to make, counsel, is that I think it's beyond the scope of the agreements that have been entered into between counsel that he's here to talk about the -- what led up to the voluntary withdrawal of the product after he left the company.

MR. TOLIN: And, Jen, I'd add topic 48 states your decisions to discontinue original Opana ER and withdraw reformulated Opana ER from the

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market, it seems to me your specific question with respect to this letter would apply to topic 48 and not the topics on which he was designated.

MS. SCULLION: So I disagree. I mean, the topic you just read, Adam, is specific to Opana ER. The topics 30 and 32 speak more generally to opioid products, as does the open letter, which goes beyond the withdrawal of Opana ER to stop -- Endo voluntarily having stopped promoting opioid products to healthcare professionals as an action to mitigate the risks of opioid abuse.

I don't want to burden the record further. It is our position that this is an area that Endo was obligated to provide a corporate representative on. We are prepared to take testimony on these issues today, and whether we do it during a break or otherwise, we'll need to take this up with the special master.

MR. LIMBACHER: Well, he's prepared to testify consistent with the

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e-mail exchanges between counsel on the processes that were in place to deal with suspected abuse or diversion consistent with the language of topic number 30 in your 30(b)(6) deposition notice.

He's not prepared and there's nothing, I don't think, in the e-mail exchanges to suggest that he should be prepared to talk specifically about the topic number 48 in your deposition notice. That is not a topic on which he has been designated.

MS. SCULLION: All right. We're going to have to do this on the record, I apologize. Topic 48 is about the withdrawal of Opana ER. The topics on which Mr. Lortie has been designated are with respect to abuse, mitigation of abuse, more generally, for opioid products, and he is, as per the e-mail, to be testifying to the substance of any changes in those policy and procedures and the reasons for those changes and

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the effectiveness of the policies and procedures.

And it's evident here that Endo made a policy decision as part of its efforts to mitigate the risks of opioid abuse, a policy decision to stop promoting opioid products to healthcare professionals, and so I am entitled to a corporate representative on that issue.

If he's not -- if Mr. Lortie is not prepared or has not been prepared to speak to that topic today, we will need to have a representative prepared to come back.

MR. LIMBACHER: He's prepared to testify on topics 9, 13, 30, 31, 32 and 39, consistent with the e-mail exchanges between counsel.

He is not prepared to testify, for example, with regard to topic number 48.

MS. SCULLION: I think we're talking past each other.

BY MS. SCULLION:

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Q. So, Mr. Lortie, let me ask you, so we can shortcut, I think, this dispute.

In Exhibit Number 5 in the second paragraph, Endo describes a number of what it calls parallel actions it has taken to mitigate the risks of opioid abuse. One is it says voluntarily stop promoting opioid products to healthcare professionals, correct? I'm just asking what it says.

A. Yes, that's correct.

Q. Okay. And it says it "eliminated the company's entire pain product sales force," correct?

A. That's what it says, correct.

Q. It also does say, "Endo voluntarily withdrew Opana ER from the market," correct?

A. That's correct.

Q. "Discontinued the research and development of new opioid products", correct?

A. That's correct.

Q. "And implemented additional anti-diversion measures," correct?

A. Yes, correct.

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Q. "Including product serialization aimed at thwarting counterfeiting and theft to protect patient safety."

Did I read that correctly?

A. You did, you read all of those correctly, and, again, it's describing those as actions taken "since," I'm reading from the document here, "our new executive leadership team began working together in September 2016."

So, yes, you read that correctly.

Q. Are you prepared as Endo's corporate representative today to speak to any of those actions Endo took to mitigate the risks of opioid abuse?

MR. LIMBACHER: Jen, he's prepared to testify consistent with what I've described now repeatedly. He's here to testify specifically with regard to topics 30, 31 and 32 as limited by the e-mail exchanges between counsel.

To the extent Exhibit 5 references issues and topics and conduct that falls outside the scope of the agreements that counsel have arrived at

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with regard to topics 30, 31 and 32, he is not prepared to testify as to that.

You can ask him questions, but that's beyond the scope of what was agreed to.

BY MS. SCULLION:

Q. So I'm just trying -- I'm trying to make sure I understand because counsel has not been clear about what is the difference between my understanding of the scope and his understanding, so I'm trying to understand what you are or are not prepared to testify to today. Let's take one particular example.

Can you identify for me today what the additional anti-diversion measures are that are referenced in this second paragraph of Exhibit 5?

MR. LIMBACHER: Object to form, object to the extent it's beyond the scope of topics on which he's designated, but go ahead and answer the question.

THE WITNESS: And I'm just going to ask for clarification when you use

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the word "additional," because I don't see that in here. So are you referring to those that are described that you just read into the record and described after occurring -- sorry -- occurring after September 2016?

BY MS. SCULLION:

Q. I am asking about steps taken after September 2016, and if you'll look at the second line from the bottom of that paragraph, it indicates one of the things that happened after September 2016 was Endo implemented additional anti-diversion measures including product serialization, and we read that, rest of that sentence before.

Are you prepared as Endo's corporate representative today to tell me what those additional anti-diversion measures were?

MR. LIMBACHER: That were implemented after September of 2016?

MS. SCULLION: That's correct.

BY MS. SCULLION:

Q. Are you prepared to testify to that today?

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A. I am not, no.

MR. LIMBACHER: I think that's outside the scope of what he was designated on.

MS. SCULLION: Counsel, is it your position it's outside the scope because it's after September 2016? I'm not clear.

MR. LIMBACHER: No, it's because it's outside the scope of what you and Mr. Davis agreed upon, which was for him to be prepared to testify with regard to the processes that were in place with regard to suspected abuse and diversion. So that's the basis for my objection.

MS. SCULLION: Well, the topic also speaks to policies and processes with respect to halting diversion, and anti-diversion measures clearly would be halting diversion. So it is our position that this is square within the topic that we need a representative on. I understand, Mr. Lortie, you're not -- you've not been prepared on that today.

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BY MS. SCULLION:

Q. Do you -- are you prepared to speak to any policies Endo adopted after 2016 with regard to product serialization as one anti-diversion measure?

A. No, I'm not prepared for that, no. I thought actually that was your last question of me so...

Q. Trying to be a specific as I can.

A. I understand.

Q. And just to be clear, are you able to speak to Endo's policy decision to voluntarily stop promoting opioid products to healthcare professionals as part of its anti-abuse efforts?

MR. LIMBACHER: And note my objection as I believe that topic in that question is beyond the scope on which he has been designated.

THE WITNESS: And I'm not prepared. Again, that happened after I departed the company.

BY MS. SCULLION:

Q. Okay. Let's go back to then I

want to ask you what did you do to prepare today to testify as Endo's corporate representative on Endo's policies and procedures with respect to abuse and diversion, including efforts to ensure compliance with applicable laws and regulations?

A. Sure. And, in fact, this is consistent with how I prepared for all of the topics I've been designated on.

I spent five or six days working with counsel, reviewing documents. I spoke to two Endo employees to help refresh my recollection of certain specific policies, procedures or identify the way certain materials had been used so I -- and I had considerable homework each evening.

So, you know, I did my best to bring myself back up to speed so that I could be helpful today.

Q. Which were the Endo employees that you spoke with?

A. We spoke with Kristin Vitanza and, also, Brian Munroe, M-u-n-r-o-e. I think that was the only two people we spoke with, if I recall.

Q. When did you speak with Ms. Vitanza?

A. Yesterday.

Q. Approximately how long?

A. How long did we --

Q. Speak.

A. 15, 20 minutes.

Q. Was that by phone or in person?

A. By telephone.

Q. And did Ms. Vitanza provide you with information that will inform your testimony today as Endo's corporate representative on any of the topics we discussed?

A. Yes, she did.

Q. What information did you obtain from Ms. Vitanza?

A. I had some specific questions on certain pieces of material, promotional material. I needed some help in understanding and recalling how they had specifically been used and with whom. She was able to clarify that.

Q. Which pieces of material did you speak about?

A. Specifically, there was a series of patient profiles called clin cases, if I'm recalling correctly. I didn't recall how they had been used, and given, I believe, some of the claims that are in question came out of those, I wanted to make sure I understood with whom they had been used and in what form the claims had been.

Q. And what did Ms. Vitanza tell you in that regard?

A. She clarified that they had been used as educational material with physicians, so we considered them promotional materials, and, therefore, those claims were subject to all of the necessary safeguards to ensure that they were well supported by medical evidence, they had been cleared by our medical, legal and regulatory team.

Q. Did you discuss any other promotional materials with Ms. Vitanza?

A. No, those were the ones in question.

Q. Did you discuss any other topics at all with Ms. Vitanza that inform your

testimony today?

A. No. She was able to answer my question.

Q. Okay. And Mr. Munroe, what did you speak with him about?

A. I asked him to refresh my recollection as to the activities specifically of the Pain Care Forum. This was relative to the topic number 39, I believe.

Q. Did you only speak to him about the Pain Care Forum?

A. Yes.

Q. When did you speak with Mr. Munroe?

A. That was also yesterday.

Q. And was that by phone as well?

A. Yes.

Q. About how long on the phone?

A. We were on the phone maybe 45 minutes or so, I think.

Q. And what specifically did you discuss with Mr. Munroe about the Pain Care Forum?

A. To the extent it related to topic

39, I wanted to understand the specifics of how that group was organized, what were the objectives of the group, who were the members to the extent -- sorry, let me rephrase that.

To what extent was it formal or informal, some of the history. I was familiar with the concept of the Pain Care Forum, but in order to prepare adequately, I wanted to get some specifics from him.

Q. And what did he provide? What did he tell you about the specifics you asked about?

A. He reminded me that this was an informal gathering of a number of stakeholders in the -- that would be interested in the world of pain medicine, policy, legislation, manufacturers, patient representatives, et cetera.

And, importantly, he reminded me that it was informal, the agenda was open. There were no positions taken by the Pain Care Forum, et cetera. I wanted clarity on specifically some of those topics, so he was able to remind me of what they did.

Q. In terms of the -- you said it was a forum for a number of stakeholders you said including manufacturers.

Do you know what other manufacturers other than Endo of opioid products were part of that forum?

MR. LIMBACHER: Jen, just so we're clear, I assume these questions are questions he is being asked in his capacity as a 30(b)(6) witness?

MS. SCULLION: That's fine.

THE WITNESS: So your question again, please.

BY MS. SCULLION:

Q. Sure. Do you know which other manufacturers other than Endo of opioid products were members of the Pain Care Forum?

A. The way it was represented to me is that the membership was evolving and dynamic. People would participate in some of the meetings, not participate in others; that literally the agenda, as well as the participation was open. So he specifically indicated that to the extent that some people would call in on a teleconference line, they were not required to identify themselves, so he -- the point he was making is this was an open forum to anyone that may be on any number of the various facets of the topic were invited to listen in, call in. So, you know, some manufacturers were there routinely. He mentioned that Purdue was often represented, and, in fact, that the -- but we didn't speak about -- he didn't identify any other specific industry attendees, because, again, that attendance was something that was fluid.

Q. And did you speak with Mr. Munroe about the relationship between the Pain Care Forum and the American Pain Foundation?

A. Not specifically.

MS. SCULLION: I apologize. We're having a technical difficulty. Off the record.

THE VIDEOGRAPHER: Off the record at 10:22.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record at 10:37 a.m.

BY MS. SCULLION:

Q. Welcome back, Mr. Lortie. You understand you're still under oath, correct?

A. I do.

Q. Thank you. We were speaking about your discussion with Mr. Munroe, and you explained your discussion of the Pain Care Forum.

Is there anything else that you discussed with Mr. Munroe?

A. No, that was essentially it.

Q. Okay. And other than Ms. Vitanza and Mr. Munroe, is there anyone else other than counsel that you spoke with to prepare for your deposition as Endo's corporate representative?

A. No.

Q. You said you spent five or six days preparing for -- to be Endo's corporate representative.

When was that?

A. It's all been in the month of January. I can't remember. We started on the 12th or 13th perhaps, and I spent considerable time last weekend, I can tell you that.

Q. Okay. And as we go through today, I'll ask you whether you've reviewed certain documents in connection with your preparation, I think that's probably the most efficient way to do that.

BY MS. SCULLION:

Q. Other than looking at documents with counsel, you said you did some home study and speaking with Ms. Vitanza and Mr. Munroe, is there anything else that you did to prepare to testify as Endo's corporate representative today?

A. No, that's the complete list of activities.

Q. And then separate from preparing to be Endo's corporate representative, is there anything else that you did to prepare for today's deposition?

A. No, same activities helped me prepare for both.

Q. Did you discuss today's deposition with anyone other than counsel?

A. No.

Q. Have you discussed this

litigation with anyone other than counsel?

A. I have not, no.

Q. Okay. And just so we can be clear and I think move on in terms of the scope of your preparation, can you just confirm for me, are you prepared today to speak as Endo's corporate representative on any of Endo's anti-abuse policies that postdate the time you worked with the company?

MR. LIMBACHER: Jen, I think we've been over this. He is prepared to testify with regard to abuse and diversion on the topics on which he's been designated consistent with the e-mail exchanges between counsel.

BY MS. SCULLION:

Q. Right. I just want to confirm because there's been some discussion about things that happened after you left and things that happened before.

Are you prepared, for example, to testify as Endo's corporate representative with respect to what Endo's current anti-abuse policies are?

A. No, I'm not prepared to do that.

MR. LIMBACHER: And I would object as being beyond the scope of the designations.

MS. SCULLION: And we disagree with that.

BY MS. SCULLION:

Q. And then, similarly, are you prepared to testify as to what Endo's current anti-diversion policies are?

MR. LIMBACHER: Same objection.

THE WITNESS: I am not. I haven't been there for over two years, so I can testify as to the activities that were underway during my employment, but not after.

MS. SCULLION: Okay. And, again, we disagree with the objection as to scope.

We're going to move on. We think we've made our position clear that these topics do fall squarely within the agreed scope of the topic. I understand counsel has taken a different position. We will reserve our rights

on that issue.

BY MS. SCULLION:

Q. Going back to your personal capacity.

A. Thank you for the clarification.

Q. When I asked you about Endo's open letter, Exhibit 5, and the reference to Endo voluntarily stopping promoting opioid products to healthcare professionals as a means of mitigating the risk of opioid abuse, you began to discuss it sounds like steps along those lines that did take place while you were with Endo. You've mentioned, I think, ratcheting down on the promotion of opioid products.

Can you tell me what -- were there any steps that Endo took while you were with Endo to limit promotion of opioid products as a means of mitigating opioid abuse?

MR. LIMBACHER: Object to form.

THE WITNESS: To be clear, there were a number of steps that Endo took to reduce promotion generally after I arrived, across all product categories,

including opioids, but also, importantly, including others.

I should also maybe point out that for the majority of the time I was there, promotion of the opioids was not, to the best of my recollection, anywheres near the most significant recipient of promotional attention or money. But, generally, for business reasons, we, I would say over the arc of my time there, ratcheted down promotional spend as well as detailing across all products.

And it's in that context that I was mentioning that there were times, in fact, with regards to Opana ER where we stopped promoting it because we were launching alternative non-opioid products but products that required attention of the sales force, so that was kind of what I was trying to explain.

BY MS. SCULLION:

Q. Can you tell me when did Endo

stop actively promoting Opana ER?

MR. LIMBACHER: Objection.

BY MS. SCULLION:

Q. You just referenced a point in time?

MR. LIMBACHER: Object to form.

THE WITNESS: Sure. And, again, just for clarification, they obviously -- and this letter helps us understand that they stopped permanently at a period of time after September 2016.

We had a period where Opana was not actively being promoted, to the best of my recollection, and that was most likely sometime in 2014. I don't recall the specific dates of stopping and restarting, but there was a period of time there where we were launching a newly acquired product and we made the business decision to have the sales force focus on the launch of that, and we took them off of Opana ER.

BY MS. SCULLION:

Q. What was the newly acquired product?

A. This was a product called Sumavel, S-u-m-a-v-e-l. It was an injectable product for the treatment of migraine.

Q. And the decision to switch the promotional efforts from Opana ER to focus more on Sumavel, you said that was purely for commercial reasons, correct?

A. Yes.

Q. It was not intended to mitigate opioid abuse, correct?

A. That's my recollection.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 6.)

BY MS. SCULLION:

Q. Handing you what's been marked as Exhibit Number 6.

MS. SCULLION: And, I'm sorry, what is the E number on this one?

MS. KUBLY: 1588.

BY MS. SCULLION:

Q. It's marked E1588 on the top right-hand corner.

Do you recognize Exhibit Number 6, Mr. Lortie?

A. No, I don't believe I've seen this.

Q. Okay. So this was not -- obviously not something you reviewed in connection with your preparation for today's deposition, correct?

A. I believe that's true. I don't recognize it.

Q. Okay. I'll represent to you that it is a copy of what's labeled as the Endo independent director's report of October 2018. Again, this is a document we retrieved from Endo's website, publicly available document.

If you could turn to what's page 1 of the document at the bottom.

MR. LIMBACHER: Take your time and review the document.

BY MS. SCULLION:

Q. I'm going to just point you to specific parts of the document. If at any point

you think you need to review more, you can let me know.

A. Thank you.

Q. Just looking at the top under "Introduction," you will see it refers to "Since its founding as a family business in 1920, Endo International plc ("we", "Endo" or the "Company") has evolved into a generics and specialty branded pharmaceutical company with an innovative suite of branded and generic medications helping millions of patients lead healthier lives."

Did I read that correctly?

A. That's what it says here, yes.

Q. And if you look briefly back at Exhibit Number 5, which was the open letter.

And you see that open letter again starts off similarly, "Since its founding as a family business in 1920, Endo has evolved into a generics and specialty branded pharmaceutical company whose products help millions of patients lead healthier lives."

Did I read that correctly?

A. Yes, you did.

Q. When you were with Endo, did Endo similarly promote its heritage going back to a family business in 1920?

MR. LIMBACHER: Object to form.

THE WITNESS: No, it didn't. In fact, I'm somewhat surprised to read that because that's not consistent with what my understanding was, but, no, we didn't promote that as part of the company message.

BY MS. SCULLION:

Q. Do you recall that there was a business by the name of Endo that was founded some decades prior to the Endo that you worked for being founded?

A. Yes, and I am aware of that in history, and my understanding was that that was a completely separate entity, even though the name was the same name and that the name was readopted after the company was established in 1999 or 2000 as a spin out from DuPont Merck. So my understanding was always that there was a disconnection between the two, other than the fact that they share a name.

Q. Is your understanding, though, that the Endo entity that was founded, as you said, as a spin-off of DuPont Merck that it acquired a portfolio of products, product rights from DuPont Merck?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: Yes, that's my understanding.

BY MS. SCULLION:

Q. And among that portfolio, there was Percocet; is that right?

A. Yes, that's correct, that's my understanding.

Q. And are you familiar with Numorphan?

A. Not specifically, no.

Q. Okay. Do you recall that among the portfolio of product rights Endo acquired from DuPont Merck were rights with respect to oxymorphone products?

A. That I don't know in detail. As you said, I recognize that Percocet and the Percocet products were part of the -- were part

of the management led buyout, but beyond that, I don't know what the specific products were.

Q. Okay. And Percocet, do you recall that's an oxycodone APAP combination product?

A. Yes, I understand.

Q. So going back to this Exhibit Number 6, the Independent Directors' Report, I'd like to get a sense from this again of what areas of Endo's risk mitigation you're prepared to testify to.

If you look to page 2 of the document, you'll see under the heading that says "Recent Risk Mitigation Efforts," this section appears to discuss the efforts since September 2016, we've already discussed that at some length about whether you're prepared to testify as Endo's rep on that.

But let me take you to the top of the next page, page 3.

MR. LIMBACHER: Jen, I'm a little confused. I thought when you handed him this document you said you were going to be asking him questions in his capacity

as a fact witness. Are we now asking him questions in his role as a 30(b)(6) witness?

MS. SCULLION: You're right. I have switched back to the 30(b)(6). Thank you very much.

BY MS. SCULLION:

Q. So now we're back in 30(b)(6) land.

A. Duly noted. Thank you.

Q. Keep saying we thought about bringing actual hats, but that won't really work too well.

So top of page 3, you see the reference in the last line of the carryover paragraph to "FDA's Risk Evaluation and Mitigation Strategy ("REMS") program"?

A. This is little (v) in that top paragraph?

Q. Yes.

A. Yes, I see that.

Q. At some point in time, Opana ER was subject to a class wide REMS, correct?

A. That's correct, yes.

Q. Are you prepared today to speak to the policies and procedures that Endo adopted to implement REMS with respect to Opana ER?

MR. LIMBACHER: Just for the sake of the record, to the extent that that subject falls within the scope of the topics on which he has been designated consistent with e-mail correspondence between counsel, he is prepared to give that testimony.

And I believe we identified for you yesterday some topics -- I'm sorry -- some documents that he was going to have in front of him, which, in fact, he does have in front of him, including, I think, the REMS document.

THE WITNESS: Yes, that's my understanding. I will only say that I'm not aware of what Endo may have done since the time I left, so to the extent that there are changes to it I'm not aware of, I can't testify to those, but, generally speaking, the REMS program I'm prepared to testify on.

BY MS. SCULLION:

Q. Okay. And then I think counsel is also referring to a document which we'll look at a little bit later, a RiskMAP.

Do you recall that prior to -- strike that.

Do you recall that REMS was implemented for Opana ER as well as all of their long-acting opioids in I believe 2012; is that right?

A. That's my understanding, yes. That was an industry wide program that was put into place that supplemented and followed but didn't replace the RiskMAP. RiskMAP had been in place since 2007.

Q. Right. So you are prepared to speak today to RiskMAP for Opana ER?

A. I am and I also -- as counsel pointed out, I have some of those documents in front of me, so we can discuss those.

Q. Right.

Are you prepared to speak to Endo's RiskMAP with respect to its generic OxyContin product?

MR. LIMBACHER: Object to the form.

THE WITNESS: I have not done that, no.

MR. LIMBACHER: I'm not sure that falls within the scope of the topics on which he's designated.

BY MS. SCULLION:

Q. Did Endo -- do you recall that Endo did for a period of time in 2004, I think 2004, 2006, sell a generic OxyContin -- oxycodone product, rather?

A. For two reasons, one being that that predated me by considerable time, and also if it was a generic, that would have been on the generic side of the business. I don't really have any particular information or knowledge on that topic.

Q. Oxycodone is an opioid product, correct?

A. Oxycodone is an opioid, yes.

MS. SCULLION: Okay. Counsel, the topic was not limited to -- certainly was not limited to the branded

opioids. It's all opioid products. That product was sold by Endo, not by Qualitest, and we do need a corporate representative to speak to Endo's policies and procedures with respect to addressing risks of abuse and diversion with respect to generic OxyContin. I understand the witness is not prepared on that today. I'm not faulting him for that. I'm just pointing it out so we're going to reserve our rights on that.

MR. LIMBACHER: I'm not sure it does fall within the scope of the topics on which he's been designated.

MS. SCULLION: We'll take it up off the record. The special master made very clear this case involves the generics as well.

MR. LIMBACHER: I'm not disputing that. The issue is what topics he's been designated on.

BY MS. SCULLION:

Q. If you'll go down to the bottom of that same page we were on, the last paragraph

speaks to "the company" -- in this case Endo -- "maintains programs for overseeing and tracking shipments for signals of potential diversion."

Do you see that sentence or that portion of the first sentence?

A. Yes, I see that.

Q. Okay. Are you prepared today to speak to Endo's programs to oversee and track shipments for signals of potential diversion with respect to any opioid products?

A. I believe this falls under the suspicious order management, so I am not prepared on that. I think we've got somebody else who is going to cover that.

Q. Okay. That's one of the things I did want to clarify.

MS. SCULLION: Counsel, is it Endo's intention to have those issues addressed by the representative designated for suspicious order monitoring.

MR. LIMBACHER: Specific to overseeing and tracking shipments, I think the answer is yes.

MS. SCULLION: Okay. The reason I ask is that's not our understanding of what suspicious order monitoring entails, but that's fine, as long as there's going to be somebody to speak to that aspect of anti-diversion.

BY MS. SCULLION:

Q. Let's continue down in that same paragraph. The next to last sentence on this page begins "Endo's Pharmacovigilance."

Do you see that?

A. Yes, I see that.

Q. Okay. And this speaks to pharmacovigilance and risk management reviewing adverse event reports received via postmarketing surveillance.

Are you prepared today to speak to Endo's policies and procedures with respect to those reviews?

MR. LIMBACHER: And, counsel, consistent with the e-mail exchanges you've had with Mr. Davis, he's prepared to testify with regard to the process of reviewing adverse event reports received

postmarketing.

MS. SCULLION: Terrific.

BY MS. SCULLION:

Q. Let me ask you this as Endo's corporate representative: The reference here to Endo's risk management department, do you know at what point in time a risk management department was established at Endo? Let me ask a better question.

Do you know when a risk management department was established that had as part of its responsibilities reviewing adverse event reports via post-marketing surveillance?

MR. LIMBACHER: And you're referencing the language at the bottom of page 3 that talks about Endo's pharmacovigilance and risk management department?

MS. SCULLION: Good point. I had separated those.

BY MS. SCULLION:

Q. Was there -- was there a separate risk management department?

A. My recollection, again, just to make sure we're all on the same page, literally, this was a report issued just a few months back, so literally two years after I had left.

That being said, I don't recall it being called pharmacovigilance and risk management department, per se. That could be something that was designated subsequent to my departure. However, those functions were all in place. We had pharmacovigilance professionals, risk management professionals, and they were operating on the, you know, both the REMS as well as the RiskMAP and other just drug safety activities that any drug company would have in place.

Q. Okay, great.

A. I'm familiar with the functions. I don't recall it being called that department, but those functions had been in place.

Q. I think counsel's clarification did help because I definitely read that as being two separate departments. Okay.

A. And my recollection it was a function that was done collectively.

Q. If you'll go to the next page, 4, under the heading "Historical and Existing Compliance Measures."

So a similar question to what we just talked about before, but the second paragraph, which refers to, in quotes, compliance department, Endo's Compliance and Business Practices Department, it says (the "Compliance Department").

Do you know when Endo established that department?

A. Endo had a compliance function, chief compliance officer reporting to the CEO as well as to the board during my entire career there.

I don't recall specifically them calling it the compliance and business practices department, again, but the compliance function was fully staffed and an important function during all of my time there, and I assume it continues.

Q. Do you know when before your time there a chief compliance officer position had been established?

A. I don't know the specific date. I know that there was a chief compliance officer in place when I joined in 2009, and there certainly was one there when I left in 2016.

Q. Okay. Let's go down to the next paragraph, which speaks to Endo's robust compliance program operated by the compliance department has continued to evolve since its establishment in 2004.

As Endo's corporate representative, are you prepared today to speak to what efforts, what compliance efforts were in place at Endo prior to 2004 with respect to opioid anti-abuse regulations and policies?

MR. LIMBACHER: Object to form and object to the extent it's beyond the scope of the topics on which he has been designated.

THE WITNESS: Specifically, I can't, I'm not prepared, I wasn't there. To the extent that they represent things that continued during my tenure, I can certainly speak to that, but I can't -- I'm not prepared to speak about what

happened prior to my arrival, specifically five years prior to my arrival here in this case.

BY MS. SCULLION:

Q. And I asked you that question with respect to compliance efforts for anti-abuse regulations.

Is your answer the same with respect to compliance efforts for anti-diversion regulations and laws prior to 2004, are you prepared to speak to those?

MR. LIMBACHER: Object to form and object to the extent it goes beyond the scope of the topics on which he's been designated.

THE WITNESS: No, I am not prepared to address those topics.

MS. SCULLION: Counsel, Endo had objected to time frame initially. That objection was resolved and the time frame objection was withdrawn, largely in response to the special master having ruled that the generics business and business other than just Opana ER was

fairly part of this case and is relevant. So, again, I understand we may have a difference of opinion. Clearly, the witness is not prepared and, again not faulting him, but we're going to reserve our rights to seek additional testimony on that period.

MR. LIMBACHER: I think he's prepared to testify with regard to the abuse and diversion policies in place that are reflected in the June of 2007 RiskMAP, which would predate his employment at the company. I don't know that he's prepared to testify with regard to policies that predate 2004.

MS. SCULLION: Right.

BY MS. SCULLION:

Q. You recall, though, that Endo was actively marketing, for example, Percocet prior to 2004?

A. I'm not sure of the timing, but, again, you've already established that that was part of the company formation, so I think that that's fair to say. That was part of our, at

that time, quite small generics business, separate from branded, and, of course, it predates me by five years.

Q. Okay. Let's go to the next page, 5, and I'm looking at the second full paragraph, it begins "in February of 2014," second sentence of that paragraph -- sorry, the paragraph is discussing the corporate integrity agreement, which we discussed earlier, correct?

A. Yes, I see the paragraph.

Q. Okay. And the second sentence says, "Pursuant to the CIA, Endo developed and implemented a Field Force Monitoring Program ("FFMP") to evaluate and monitor its sales representatives' interactions with HCPs."

And, again, I'm asking you this in your capacity as Endo's corporate representative, what was the Field Force Monitoring Program?

A. So I will say that both the acronyms here, the FFMP and the NPMP I'm not familiar with. I don't know if subsequent to my departure they decided to put into place nomenclature to help, you know, understand or be

able to describe these.

That being said, I'm familiar with many of the aspects of the CIA. As we've said before, I was a signatory on that, and, in fact, field force monitoring, which for me encompasses everything from selection and training to monitoring the activities and dealing with if any cases arose where the sales force was acting outside of the well-established rules and regulations, that I am familiar with. I have just not seen it called specifically the Field Force Monitoring Program.

Q. So I take it you could not answer for me today that the extent to which the development and implementation of what's labeled here as a Field Force Monitoring Program, you couldn't tell me how that may have changed any of the procedures with respect to overseeing compliance with laws and regulations governing sales representatives' interactions with healthcare providers?

MR. LIMBACHER: Object to form. I think you misstated his testimony.

THE WITNESS: Within the

construct of the CIA, I can certainly discuss some of the -- as you say, the changes, which for me, to my recollection, were about memorializing recordkeeping reports, cooperation with the Department of Justice on the aspects of the CIA to ensure company compliance with those things.

For me, importantly, activities with regards to field force and interactions with HCPs, et cetera, really do link back to the RiskMAP and then subsequently the enhancements to the RiskMAP as represented by the REMS, as we've spoken. So I think all of these things are fundamental to how Endo trained, monitored, reported activities related to its sales reps and commercialization.

BY MS. SCULLION:

Q. And we will talk about RiskMAP, but you don't, sitting here today, know whether the Field Force Monitoring Program referenced here changed any of the policies or procedures

that you were familiar with under the CIA or RiskMAP?

A. I'm sorry, I was about to answer, but your question actually confused me, so could you just ask that again, if you would.

Q. Sure.

Sitting here today, you don't know whether the development and implementation of what's called here a Field Force Monitoring Program, whether that changed any of the policies or procedures that you're familiar with under, let's start with the CIA?

A. The nomenclature Field Force Monitoring Program is not one that I'm recalling here, and I'd be happy to look at documents, maybe that would help me recall it. That being said, I'm well aware of certain changes to policies and procedures that were made within the content and the construct of the CIA, again, on topics of reporting and signing and board resolutions, et cetera.

So to the extent that that's what's being referred to here, I can do my best to speak about those, but, you know, the FFMP as

a specifically designated program, I would need to see something to help me see whether or not I could add to that.

Q. Okay. And if you go two paragraphs down, the paragraph begins, "The compliance department has also implemented a risk assessment and mitigation process (RAMP) to standardize and centralize risk assessments relating to promotional activities."

Are you prepared as Endo's corporate representative to speak to the RAMP process?

MR. LIMBACHER: Object to the extent that that calls for him to testify beyond the scope of the topics on which he's been designated as described in more detail in the e-mails between counsel.

MS. SCULLION: Again, we'll disagree that it's beyond the scope.

BY MS. SCULLION:

Q. Are you prepared to speak to that?

A. Again, with regards to the

designation of this RAMP, that's not a -- that's not an acronym that I'm familiar with, so this may have come together in the period of time after I left.

Having said that, I can certainly speak to activities related to promotional activities, risk assessment activities undertaken that I think is in here, but I can't attest to whether or not that's complete under this topic of RAMP because I don't recognize what RAMP -- the complete details of what RAMP may refer to.

Q. Okay. If you go to the next page, 6, the heading "Review and approval of promotional materials," you see this first paragraph refers to the "Marketing and Advertising Review Committee ("MARC")"?

A. Yes. Again, I'm going to just take a minute and read the paragraphs here just to orient myself.

Q. Sure.

A. (Witness reviews document.)

Okay, I've read that section. Thank you.

Q. Okay. And I think you explained earlier you're now prepared to testify to Endo's policies and procedures implemented through MARC with respect to opioid products, correct?

A. Yes, I think I'm well prepared for that.

Q. Okay. And to be clear, the predecessor to MARC was the PMRB, correct?

A. Yes.

Q. And you're prepared to testify to the policies and procedures used by the PMRB with respect to opioid products, correct?

A. I believe they're essentially one in the same, to my recollection, so yes.

Q. That's what we're going to get to.

If you go to page 7, the heading "Identification of healthcare providers eligible for; sales calls."

Do you see that heading?

A. I do.

Q. And then the second paragraph down, the second sentence says, "The company's Abuse and Diversion Detection Program ("ADD

program") has included," and then it lists a number of items there.

Are you familiar with the company's ADD program referenced here?

A. I am in general. Again, it's -- I'm familiar with that acronym. It really -- all of these link back to the RiskMAP, the REMS in terms of policies and procedures the company had in place for many years to accomplish the objectives set out here and explained here.

Q. I think I misheard your testimony, but you are not familiar with the ADD --

A. I'm familiar with that acronym.

Q. You are?

A. I am, yes.

Q. Okay, I heard wrong. Thank you.

A. Sorry, my mistake.

Q. No, no, I heard incorrectly.

Okay. And I think you said you're prepared to speak to that today as Endo's corporate representative, correct?

MR. LIMBACHER: To the extent that it falls within the scope of the

topics on which he's been designated, yes, he's prepared.

MS. SCULLION: Okay.

THE WITNESS: Just for clarity, within the documents here that I have to refer to in real time, we have the RiskMAP and the REMS. I don't think we have the ADD document specifically, so it may be that I need some help, but if you've got some specific point in that, something that I can refer to, but, generally, I'm prepared to address that topic.

BY MS. SCULLION:

Q. You stated -- you referred to an ADD document.

Was there a specific ADD document similar to RiskMAP?

A. My recollection is that the ADD specifically as described, the ADD followed the agreement with the New York Attorney General a few years back, shortly before I left, and, as I said before, my recollection is the majority of that memorialized activities that the company

had been involved in for years. But if there's a specific part of it, I may need to ask to refer to a page in that agreement with the New York Attorney General to refresh my specific recollection.

Q. Got it. Thank you.

And then the last paragraph on this page 7 does speak to suspicious order monitoring programs, and I think we discussed that there's going to be a separate corporate representative on those issues.

But let's take off your corporate representative hat then for the moment. Just based on your experience at Endo, was there any -- was there any connection between the ADD program and the SOM programs at Endo?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. Were those sort of separately run programs I guess is the question?

A. Well, I don't know how to answer that in that the -- you know, to my understanding, the suspicious order monitoring program was done in the context of all of the

steps the company took for risk management, mitigation of potential abuse, diversion, training, et cetera, again, linking back to the RiskMAP and the REMS, so I wouldn't say that you can necessarily split one and say that the SOM program was not in the context of the spirit of the ADD as it was in the spirit of RiskMAP and REMS as well.

So I think, if I understand your question correctly, I would say that, no, you can't really separate those things. There was SOMS and all the other steps were done in concert with the goals of the ADD and the other things we had in place.

Q. Was there any one individual charged with overseeing the ADD program?

A. No, not to my recollection specifically. Again, the ADD, given that it was a follow on and in the context of the RiskMAP and REMS and all of the policies, procedures and activities really the responsibilities either specifically by function or collectively by executive team all the way up to the CEO and the board, I would say everybody had accountability

for making sure that the company was acting appropriately.

Q. Okay. But there was no one specific person charged with overseeing it?

A. Overseeing ADD specifically?

Q. Yeah.

A. Not to my recollection.

Q. Okay.

A. Again, ADD, my recollection, was a memorialization of things -- many things that were already in place that really crossed -- were cross-functional in nature.

Q. And with respect to SOM programs, was there an individual charged with overseeing Endo's SOM programs?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. I can ask this in your personal capacity.

A. Yeah, to my recollection, again, personal capacity and thinking of the branded business, one of our supply chain managers oversaw two aspects that I think are relevant to the question. One is Endo's branded SOP with

regards to that activity and specifically, also, oversight of our distribution partner, our sole distribution partner for the branded business, which was UPS. UPS being the DEA license holder had ultimate responsibility for managing and maintaining their specific program, but that was my understanding.

Q. And you said there was a supply chain manager. Was that Ms. Walker?

A. That was Lisa Walker, yes, at least during the time that I recall.

Q. One more thing, in that same exhibit, the independent director's report, turn to page 4, Exhibit Number 6 again.

Bottom of page 4, the last paragraph, last sentence says, "Endo's compliance program incorporates the fundamental elements of an effective compliance program including," and then there are bullet points at the bottom of page 4 that extend over to the top of page 5. I'm asking this in your capacity as Endo's corporate representative, were these fundamental elements of an effective compliance program applicable to Endo's compliance program

for the entirety of time that Endo sold opioid products?

MR. LIMBACHER: Object to the extent it falls outside the scope of the topics on which he's been designated.

MS. SCULLION: Again, we disagree with that.

THE WITNESS: Well, as explained here, this is discussing the establishment in 2004, which I wasn't aware of for an earlier question, and it explains that the compliance department and the policies and procedures have continued to evolve since that point in time.

With regards to Opana, which was launched in 2006 or Opana ER -- sorry -- Opana ER and Opana, I believe, were both launched in 2006 and my arrival in 2009, this is consistent with my recollection for that period of time. Prior to that, I can't attest to what happened.

BY MS. SCULLION:

Q. Okay. So --

A. Or what the policies and procedures were.

Q. Okay. So you'd agree that with respect to compliance -- sorry.

With respect to enforcing, for example, the regulations and laws and policies for anti-abuse for opioids, that these fundamental elements of an effective compliance program would apply to such compliance efforts, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm really sorry, I really don't understand that question.

BY MS. SCULLION:

Q. Sure, try that one again.

A. Yeah.

Q. Well, you're here to speak today in part as Endo's corporate representative on Endo's efforts to ensure compliance with anti-abuse laws, regulations and policies, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: To the extent that it's in the topics designated, yes.

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BY MS. SCULLION:
Q. Okay. And same thing with respect to anti-diversion laws, regulations and policies, you're here to speak to Endo's compliance efforts with -- to ensure compliance with those laws, regulations and policies, right?
MR. LIMBACHER: Object to form.
THE WITNESS: Yeah, with the exception of specific detail on SOMS, that's my understanding.
BY MS. SCULLION:
Q. Correct, thank you.
And you'd agree that for those compliance efforts to be effective, they would need to, for example, have as indicated in the first bullet point here, clear rules, clear set of rules?
MR. LIMBACHER: Object to form.
THE WITNESS: That sounds reasonable.
BY MS. SCULLION:
Q. Written down somewhere?
A. I would think so.

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Q. Okay. And there needs to be training on those rules and efforts to assess the effectiveness of those rules --
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. -- effectiveness of the training?
MR. LIMBACHER: Object to form.
THE WITNESS: That sounds like a reasonable, reasonable statement.
BY MS. SCULLION:
Q. There should be records kept of the compliance process, correct?
A. I think you're asking me just to explain what a rigorous compliance program would be. In my experience, during my time there, as well as at other companies, those things that you're mentioning sound like reasonable aspects of a typical compliance program.
Q. Let's just make sure then that we're on the same page on that.
So we said clear rules, yes, written down, yes, correct?
A. I would think that would be reasonable, yes.

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Q. We talked about training and assessing the effectiveness of the training, also reasonable?
MR. LIMBACHER: Object to form.
THE WITNESS: I think that's reasonable.
BY MS. SCULLION:
Q. Keeping records so they could be subject to audit, correct?
A. Again, sounds reasonable.
Q. To then actually go in and audit records of compliance, that would also be a reasonable part of a compliance program?
MR. LIMBACHER: Object to form.
THE WITNESS: Probably have less particular knowledge about audit procedures as they -- as they pertain to compliance in general, so I'm not -- I'm less sure about that specifically. I know that under a CIA, for example, there are explicit rules and audit reporting. I'm not sure -- you're kind of describing a general concept for good compliance. So, you know, in that

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context, I'm not sure about the audit requirements or what would or would not be reasonable. I'm not an audit professional, for example.
BY MS. SCULLION:
Q. Okay. Would you agree that consistent discipline measures to ensure compliance would be a part of a reasonable compliance program?
MR. LIMBACHER: Object to form.
THE WITNESS: I would agree with that, yes.
BY MS. SCULLION:
Q. How about what's called tone at the top. Are you familiar with that phrase?
A. Generally I've heard that, yes.
Q. Okay. Well, let's look on page 4 of Exhibit 6. If you look at the last bullet point there it says, "Effective lines of communication including messages from senior level leaders regarding commitment to compliance."
Is messages from senior level leaders regarding commitment to compliance, is

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that's what referred to as tone at the top?
MR. LIMBACHER: Object to form.
THE WITNESS: I think that's consistent with my understanding of the term, yes.
BY MS. SCULLION:
Q. Okay. Would you agree it would be inconsistent with a reasonable compliance program if the tone at the top was that an anti-abuse policy was, quote, unquote, window dressing?
MR. LIMBACHER: Object to form.
THE WITNESS: Would I agree that it would be inconsistent and did you say that a senior leader would be the person writing or communicating?
BY MS. SCULLION:
Q. I'm sorry, that a senior leader would -- would, yeah, refer to an anti-abuse program as window dressing.
MR. LIMBACHER: Object to form.
THE WITNESS: It would be most helpful if there was a specific instance of communication so that I could

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understand the context of the person, how we are describing senior leader. With those qualifications, in my opinion, yes, that would be correct, that that would be inconsistent with tone from the top.
BY MS. SCULLION:
Q. So, for example, if a vice president of regulatory affairs were to refer to an anti-abuse program as being your window dressing, that would not be consistent with a message from a senior level leader regarding commitment to compliance, right?
MR. LIMBACHER: Object to form.
THE WITNESS: I actually see it a little bit differently. Not that that -- not that that communication wouldn't be troublesome, but when I think of tone from the top, I think of in the context of senior leadership communicating to large sections of the corporation that, you know, the company -- that tone from the top to me is proclamations from or, you know,

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discussions of what's important from the CEO or other members of the leadership team. Again, it would be most helpful to see a specific communication so I could understand the context, but tone from the top is a little bit different to me than what you just described, but it could be that when I see some detail, it would help me understand better.
BY MS. SCULLION:
Q. You would agree that tone from the top is not just the words uttered, it has to be sincere, correct, a sincere tone?
A. Sincere and words and actions matter, that's my own personal policy.
Q. And if a executive at the vice president level regarded an anti-abuse program as mere window dressing, that would not be consistent with having a sincere belief and commitment to compliance with that anti-abuse program, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Again, as mentioned before, it would be most helpful if

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there was a specific instance and a specific person and a specific audience I could review, and then I could give a more fulsome answer to that.
BY MS. SCULLION:
Q. Okay. And with regard to Endo's approach to ensuring compliance with -- let's start with compliance with the laws and regulations governing promotional materials --
A. I'm sorry. I coughed literally when you said an important word. So before you say the whole thing, could you start again.
Q. Absolutely.
In terms of Endo's approach to ensuring compliance with laws and regulations, let's start with laws and regulations that govern the promotion of pharmaceutical products, did Endo regard it as appropriate for -- to be looking for ways to evade the applicable laws and regulations?
MR. LIMBACHER: Object to form. Are we now asking him questions in his capacity as a 30(b)(6) witness?
MS. SCULLION: This is in his --

yes, 30(b)(6), yes.
MR. LIMBACHER: So we've switched over, okay.
THE WITNESS: So if I understand your question, did Endo find it to be appropriate to seek ways to evade the promotional rules and regulations?
BY MS. SCULLION:
Q. Yeah.
A. Absolutely not.
Q. Do you think it should be, you know, coming right up to the line of those laws and regulations and pushing the envelope?
MR. LIMBACHER: Object to form. Object to the extent it falls outside the scope of his 30(b)(6) topics.
THE WITNESS: No, that's not my recollection.
BY MS. SCULLION:
Q. So, for example, would it be appropriate for Endo to have taken a position with respect to promotional materials with the understanding that its position was likely to draw a warning letter from the FDA?

MR. LIMBACHER: Same objections.
THE WITNESS: Absolutely not.
BY MS. SCULLION:
Q. Was it appropriate to essentially roll the dice and say, let's give it a try and see if we get a warning letter, and if we do it's not a big deal?
MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics on which he's designated.
THE WITNESS: No.
MS. SCULLION: And just to be clear, I disagree with the scope objections.
Counsel, if we can have an agreement that I don't need to keep saying that?
MR. LIMBACHER: Yes, I agree you do not.
MS. SCULLION: Assume I don't necessarily agree with your scope objections.
MR. LIMBACHER: I understand.

MS. SCULLION: Thank you, okay.
BY MS. SCULLION:
Q. Again, continuing in your capacity as a corporate representative, I want to focus in on Endo's policies and procedures to combat diversion of opioid products. So do you know whether those policies -- start with policies -- whether Endo's policies in that regard changed over time?
A. Again, our policies around the mitigation and prevention of abuse and diversion are all rooted in the RiskMAP, and that has been consistent through the period of time that I was there, and I believe -- I would be surprised if it doesn't continue to underpin the company's activities. As we've previously discussed in 2012, an industry-wide component of the same objectives was incorporated. That would be the industry-wide REMS for opioid products. So that was a continued evolution. To the extent that I would say it changed the fundamental objectives, probably not, but it was an evolution, and then we've also spoken about certain aspects as memorialized in the New York Attorney General

ADD program. To the extent that that happened later and memorialized some of the things that had happened before and perhaps there were one or two changes, I'd have to look, but, generally, I would say that Endo's policies, procedures, activities, measurements, et cetera, always have fundamentally been rooted in those that are set out in the RiskMAP.
Q. Okay. And as to policies that predate the RiskMAP, you're not prepared to speak to those, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: That's correct.
BY MS. SCULLION:
Q. Do you even know whether Endo had any policies, any anti-diversion policies in place prior to the implementation of RiskMAP in 2007?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't have specific knowledge of that. I really look to RiskMAP as being the fundamental foundation of all of that activity. That's not to say that I would suspect

that they were not being a compliant organization, but RiskMAP to me is really the fundamental set of policies, procedures, activities surrounding those topics.

BY MS. SCULLION:

Q. Okay. And we were just speaking about anti-diversion policies. Same questions with respect to anti-abuse policies, did those fundamentally change over time at Endo with respect to opioid products?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm including that in sort of the same answer as with diversion because abuse, diversion and all of the other aspects were really the fundamental goal and objective of RiskMAP and everything that followed from that.

BY MS. SCULLION:

Q. Make sure that I understand that last answer.

In terms of anti-abuse and diversion policies, was there any distinction

between what was considered abuse and what was considered diversion; was all abuse diversion and all diversion abuse?

MR. LIMBACHER: Object to form.

THE WITNESS: No. I think that there are separate components but they all are under activities that the company was highly focused on to prevent both of them as they pertain, in particular, to the manufacture, distribution and promotion of controlled substances.

MS. SCULLION: Okay. Can we have the RiskMAP.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 7.)

BY MS. SCULLION:

Q. Hand you what's been marked as Exhibit Number 7, and Exhibit 7 is Bates stamped ENDO-CHI_LIT-00234542.

Mr. Lortie, do you recognize -- we'll go back to your personal capacity for the moment.

Do you recognize Exhibit Number 7?

A. Yes, I do.

Q. And is this a copy of the June 2007 RiskMAP for Opana ER?

A. It is, yes.

Q. And this is one of the documents that you did review to prepare for today's deposition, correct?

A. That is correct.

Q. Now, this is indicated as a RiskMAP for Opana ER, and it obviously details a number of programs, initiatives, efforts to be undertaken as part of this RiskMAP.

Endo did not, though, have a RiskMAP for Opana IR, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I am not aware of whether they did or did not. I am aware of this document being developed specifically in the context of the launch in 2006 of Opana ER, which being an extended-release opioid, the company felt it was responsible to put together

this comprehensive program. As to IR, I don't know.

BY MS. SCULLION:

Q. And in June 2007, the company was also -- Endo was also selling Percocet, correct?

A. Again, Percocet was managed at that point in time, I believe, by the generic division, but I think, yes, I believe they were distributing it. I don't think they were actively promoting it, but I'm not sure. Again, that predates me.

Q. And do you know whether Endo had a risk management plan for Percocet?

MR. LIMBACHER: Object to form.

THE WITNESS: I don't know whether they did or not.

BY MS. SCULLION:

Q. Okay. So I take it you also couldn't speak to, for example, why Endo had a RiskMAP for Opana ER but not for IR?

MR. LIMBACHER: Object to form, misstates his testimony.

THE WITNESS: Correct, because I don't -- there could have been one, I

just don't know. So it's hard to -- but I can -- this to me was really the collection of company activities with regards to long-acting opioids, in my view.

BY MS. SCULLION:

Q. And that's one of the questions I have is the activities identified in Exhibit 7, the RiskMAP for Opana ER, did those apply to any other opioid products that Endo was selling at that point in time?

MR. LIMBACHER: Object to form.

THE WITNESS: Well, again, with the exception of Opana IR, I'm not aware that the company was selling any other opioids at that period of time, within the -- you know, by "selling" I mean promoting. We've already established that they were distributing Percocet and there may have been other generics, but I'm aware of this, again, from the perspective of the branded business and active promotion.

MR. LIMBACHER: Jen, we've been

going about an hour, whenever there's a good time for a break.

MS. SCULLION: Yeah, we can do that.

MR. LIMBACHER: Thank you.

THE VIDEOGRAPHER: Going off the record at 11:39 a.m.

(Brief recess.)

THE VIDEOGRAPHER: We are back on the record at 11:56.

BY MS. SCULLION:

Q. Welcome back, Mr. Lortie.

A. Thank you.

Q. Put your corporate representative hat on.

One aspect of diversion with respect to opioid products are what is called pill mills, right?

A. Yes, pill mills, yes, I'm familiar with that term.

Q. And just so we're on the same page, what's your understanding of what a pill mill is?

A. My understanding that would be

some source of -- some inappropriate source of acquiring controlled substances for the purpose of using them outside of their intended medical use. So, for example, a physician's office who was prescribing said medicines for purposes other than their intended labeled use.

Q. Okay. And what procedures did Endo have in place to monitor for pill mills? Let's start with respect to Opana ER.

A. Sure. You know, if we want to go into detail, that would be a good point to refer back to the RiskMAP.

Q. I'm happy to do so. We have -- we've marked the RiskMAP, it's in front of you.

A. Okay, that would be --

Q. So if there are pages -- and for the record again, this is Exhibit Number 7, if there are specific pages within the RiskMAP that help, why don't you point those out to me?

A. Sure. I'm looking at the table of contents. If you just give me a moment, I'll go down.

Q. Sure.

A. Just generally, the policies and

procedures included, first of all, training of our sales representatives who were responsible for calling on healthcare practitioners, giving them certain education in terms of what would be -- constitute a suspicious policy or procedure at a physician's office. Just give me a moment to look for the specific topics here.

Q. Sure.

A. I mean, what comes most immediately to mind is literally there is a form that existed, and I assume most likely still exists, that representatives were instructed to use if they had suspicions that a healthcare practitioner that they were -- that was on their call list or the list of approved customers exhibited a number of -- any number of suspicious activities, and I think that's -- if that's not in here, it's in the binder, and I can refer to that maybe.

Q. So in terms of procedures to monitor for pill mills, you've identified sales reps in the field being trained it sounds like, I'm paraphrasing, to look for sort of the hallmarks of a pill mill, correct?

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A. That's correct.
Q. And there's a -- there was a form to be used to report up if a rep believed they saw the hallmarks of a pill mill, correct?
A. That's correct.
Q. Anything else, any other procedures that Endo had in place to monitor for pill mills with respect to Opana ER?
A. Sure. I mean, as a result of the activities that you just described very well and accurately, filling out the form that had a number of attributes that would constitute a suspicion that a given practice was operating inappropriately, that form would be submitted by the representative to the compliance department, the legal department and his or her direct manager.
That would institute or set into motion an investigation by someone in our legal and/or compliance department to investigate whether or not the evidence was corroborated, and, if so, the physician was removed from the call list so that that representative would no longer be allowed to call on or be asked to call

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on that physician.
So that was -- you know, that's sort of the foundation of how the company dealt with suspicious offices that gave us an indication that perhaps they weren't operating as an above board healthcare practitioner office.
And I can read through. I mean, there are several attributes that help to explain what that looked like. If you'd like I'd be happy to give you an example of a couple of those.
Q. I'm not sure what you're referring to. If there's something in the RiskMAP specifically that you think I -- we should be looking at --
A. Well, I think these --
Q. -- that addresses this issue?
A. These are consistent certainly with the RiskMAP, but, you know, you had mentioned a couple of them, you know, the attributes that would -- that would cause a sales representative to suspect that there was a --

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Q. Hallmarks of pill mill is what you're talking about?
A. Exactly, so, you know, proportion of prescriptions being paid for in cash, people lined up outside the door, law enforcement presence around. Including also if a sales representative saw something in the media that pointed to inappropriate behavior by his or her physician, they were required to report that as well, and that would be part of what the legal and/or compliance department officer would use as their investigation of the allegations.
Q. So you've just described a procedure by which, again, the sales reps, if they see something or they hear of something potentially in the media that causes them to be suspicious that a physician -- strike that -- a healthcare provider on their call plan may be a pill mill, that they then escalate that up through a reporting process, and there's an investigation process that occurs, and if there's corroboration the healthcare provider is removed from the call list.
Were there any other procedures

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that Endo had in place, other than what you've just described, to monitor for pill mills with respect to Opana ER?
MR. LIMBACHER: Object to form.
THE WITNESS: Yeah, there was -- and, again, these are outlined in Exhibit Number 7 that you handed me the RiskMAP in there, and if you go through the table of contents, there's a number of different topics that would satisfy what you just said. I'm looking at media screening, for example.
BY MS. SCULLION:
Q. If you could give me the section numbers as you're looking through the table of contents.
A. Sure. So I'm looking on page 3 of the table of contents, and I'm looking at Section 3.5.2.6.
Q. Media screening?
A. Media screening would be one. And, again, if we turn to page 28, we can see more specifics on that in this document. Going down a couple more, I believe the Quantitative

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Internet Surveillance Program was part of that as well, 3.5.2.9.

And then 3.2.4.3 it outlines, you know, more or less what we just said about sales force compliance.

And then, you know, a number of all these other initiatives related to education, training of sales force, of physicians, of other healthcare practitioners, of patients are all part of the -- part of the RiskMAP itself.

And then also, I believe, appendix number 2, it could potentially be helpful here, which is a list of -- and appendix number 2 I believe is on page number 42 of the exhibit. And while this is more about distribution channel, it speaks to the number of steps that Endo had in place to be alert for safeguard and prevent opioid diversion. Again, not specifically relating to sales force, but specifically relating to the production and distribution of the product. So that's not specifically in response to your answer on pill mills, but I think it's helpful because it

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underpins the foundation of the activities the company undertook.

Q. On that last point, let's make sure I understand, staying on page 42 is appendix 2, "Endo Safeguard to Prevent Opioid Diversion." Do I understand this appendix really speaks to the distribution chain?

A. Yes, that's what -- and I was trying to explain that, the supply chain is what I called it.

Q. I'm glad you said that because I do get confused with the reference to supply chains, in my mind distribution chain, okay.

And I think you said earlier that the prevention of diversion within the supply chain is what you referred to broadly under the heading as suspicious order monitoring, correct?

A. So just to clarify a couple of points, for me the difference between distribution chain and supply chain is really the top row here, which is the production of the material.

Q. That's the supply?

A. And then it's distributed through

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the network of wholesalers, distributors, retail pharmacists, you know, many different nodes in that distribution channel that in combination with the production constitute for me the supply chain. So that's what I think of when I think of supply chain.

Suspicious order monitoring certainly falls within one of the activities to prevent diversion that occurs at the appropriate levels within the distribution channel or that part of the supply chain.

Q. Okay. So staying on this page 42, appendix 2, the first line, as you say, is -- speaks to preventing diversion at the factory, correct?

A. Correct, or even before the factory with inbound material.

Q. Inbound material?

A. Right.

Q. So but, certainly, this is not speaking to a process that would monitor for pill mills?

A. Correct.

Q. Fair? Okay.

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A. That's right.

Q. So, to be clear, there's no healthcare providers involved at that stage, right?

A. Correct.

Q. And, by the way, it says at the factory, in 2007 did Endo itself have any manufacturing facilities for opioid products?

MR. LIMBACHER: Object to form.

THE WITNESS: I believe the answer is no. Again, that predates me, but my understanding is that that's not the case, but still, those who did were responsible to make sure that these safeguards were in -- or equivalent ones were in place.

BY MS. SCULLION:

Q. Okay. Was Endo itself overseeing anti-diversion efforts at the factories that it didn't own?

MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics on which he has been designated.

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THE WITNESS: So my general understanding and the way I've always looked at this is that -- and I believe it's consistent with the FDA is that Endo has the -- as the party responsible for commercializing and selling shares that responsibility with the manufacturer, and those things are often contractually agreed to. So I don't separate them generally one versus the other. In other words, I think the manufacturing facility would have had its own set, if not the exact same ones, that Endo was requiring them to, but I can't attest to that because I don't have a visibility to that specific, but, generally, I think of that, that both parties shared the responsibility.

BY MS. SCULLION:

Q. Right, so but you're not prepared to testify today --

A. That's correct.

Q. -- as Endo's corporate representative with respect to Endo's policies

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about ensuring against diversion at its contracted -- sorry, contractual manufacturers, correct?

A. Specifically, I think you're correct.

Q. Okay. And the next line on appendix 42, it says "In transit to the distribution center," so, again, that's not speaking to monitoring for pill mills, correct?

A. Correct.

Q. Okay. And I think you referenced this earlier, but, again, in 2007 did Endo have its own -- did Endo, own the distribution center through which Opana ER was distributed?

MR. LIMBACHER: Object to form.

THE WITNESS: No, I don't think Endo ever owned a distribution center, to my knowledge.

BY MS. SCULLION:

Q. Okay. And are you able to speak today to Endo's policies with respect to ensuring that its contracted distribution center had sufficient anti-diversion procedures in place?

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MR. LIMBACHER: Object to form and object to the extent it falls outside of the scope of the topics on which he has been designated.

THE WITNESS: Yeah, I think specifically by definition what you're asking is the suspicious order monitoring program because that defines what the distribution center has, so I believe you have another witness that will represent the company on that topic or that portion of the topic.

BY MS. SCULLION:

Q. And just to again confirm, the next line says, "At the distribution center," again, that distribution center, that's not Endo, that's UPS, right?

A. Whether it was in 2007, I think, but for the time period that's most important, that was UPS and still is, I think.

Q. And, again, this line does not speak to monitoring for pill mills, right?

A. That's correct.

Q. And similar to the last line on

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this page, it says "To the wholesale distributor, institution or pharmacy."

Was there anything in the processes described in this line of appendix 2 that went to monitoring for pill mills?

A. No. This really describes the diversion activities that are taking place in the supply chain.

Q. Okay. Let's turn to Media Screening you referenced. 3.5.2.6 is page 28.

Can you explain to me how the media screening process described, pages 28 and 29, how that was used to monitor for pill mills?

A. Media screening generally was searching for a number of -- a number of topics, and they're outlined here, including Opana, oxymorphone, abuse, misuse, opioids and some others, and the screening, among other things, would capture law enforcement reports or other reports in the media, and to the extent that they involved our products, in some cases, would be able to give the company an indication that a given practitioner had either been under suspicious of, investigation of or was being

prosecuted for pill mill activity or inappropriate activity. So that's why I represented that media screening was one of the tools that the company used to stay -- to the best of its ability stay apprised of some of those potential activities.

Q. Okay. So fair to say media screening here as it relates to monitoring for pill mills is dependent on someone else already having identified an actual or suspected pill mill and reported that in the media, correct?

A. I think that that's correct, yes.

Q. Generally, those reports would come once law enforcement had, in fact, arrested or prosecuted someone for being a pill mill, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I think generally that's correct, yes.

BY MS. SCULLION:

Q. Okay. And then you referred to a Quantitative Internet Surveillance Program, Section 3.5.2.9.

A. Yes, I did.

Q. And this -- it's called the QISP. Is this similar to the media screening?

A. I think it's similar, although it's a little bit more specific in that it's looking for specific mentions of, in this case, the specific prescription drugs including Opana ER in what I would call internet chatter often amongst communities of abusers. So it's slightly different, although they certainly -- there certainly were likely to have been cases where that chatter was related to or following something that had been picked up separately in the media, but it's not exactly the same thing. This is focused more on general mentions in communities of abusers as opposed to media screening for law enforcement intervention and the like.

Q. Now, if you look at what's written in Section 3.5.2.9, it says in the very last sentence, "The QISP will be used to monitor mentions of Opana ER as well as other relevant comparators for any apparent trends in abuse of the product among prescription opioid abusers."

Did I read that correctly?

A. Yeah, that's what's written here.

Q. And so this portion of the RiskMAP is really going to looking for abuse trends, correct?

A. Among other things, that would -- my read of this is that that was one of the -- one of the possible outcomes of that activity.

Q. Is there any mention in this Section 3.5.2.9 of using QISP to monitor for pill mills?

MR. LIMBACHER: Object to form.

THE WITNESS: Not explicitly but, you know, again, if you consider what internet chatter could be picked up, it wouldn't be unreasonable to suspect that there could be occasions where abusers are mentioning either a pill mill where they've had successful access or one that they longer have access. I mean, I'm just thinking of two potential -- so I certainly would count this as one of the ways that the company was responsibly doing their best to be aware

of potential occurrence of pill mill type activity.

BY MS. SCULLION:

Q. Who was responsible for monitoring the QISP data?

A. This, to my recollection, would have come into our drug safety pharmacovigilance department, so we had a set of trained medical-legal professionals who would be responsible for all aspects of drug safety and monitoring and liaising on those topics, and this would have fallen under that.

Q. It wouldn't have come into, for example, the compliance or legal department you mentioned earlier who would be responsible for responding to sales reps' reports of suspected pill mills, right?

MR. LIMBACHER: Object to form.

THE WITNESS: No, I would disagree. I mean, compliance and legal would have had full view to any alerts that were coming out of pharmacovigilance or drug safety, in general. That's not even just related

to our opioids. That's related to all products.

BY MS. SCULLION:

Q. Do you know for a fact whether anyone in compliance was looking at QISP results to monitor for pill mills, whether that was a specific thing that they were doing?

MR. LIMBACHER: Object to form. Object to the extent it falls outside the scope of the topics on which he's been designated.

THE WITNESS: I think my previous answer answers that question. Drug safety, pharmacovigilance group that was monitoring this, as well as other components, should there have been an alert, the legal department, appropriate compliance representatives would have been aware.

Same thing if one of our sales representatives reported up through their leadership of a suspicion, eventually those topics would have all come into the compliance and legal

group.

BY MS. SCULLION:

Q. And is there any written protocol that would state that the pharmacovigilance and I think you said safety --

A. Drug safety.

Q. -- drug safety professionals had responsibility to monitor this data to -- for signs of suspected pill mills?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not sure whether it's designated such as that, but, again, by nature of the data of it in this particular instance that they're monitoring, any signs or signals of inappropriate activity with regards to any of our products would have been something that they would have acted on and alerted and, again, regardless of whether it was relative to a pill mill or other diversion activity or untoward side effects or adverse events with the products, that was the job of this group, and they -- so I would suspect

they probably had operating procedures. I can't tell you what those were myself, but it could be that they're in place.

BY MS. SCULLION:

Q. I'm sorry. If I asked you the question again as Endo's corporate representative, and I apologize if I wasn't clear, these questions have been in your capacity as Endo's corporate representative.

Do you know as Endo's corporate representative whether there was, in fact, a policy that required the pharmacovigilance and drug safety personnel to monitor the QISP data for suspected pill mills?

MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics on which he's been designated.

THE WITNESS: On that particular -- the way you phrased that, sitting here right now, I do not know whether or not they did, but in terms of general practice, I think I've explained that that would happen. Whether or not

there's a specific SOP that designates the QISP and activities regarding pill mills, I think that's getting very, very specific.

My testimony is that that falls into their job responsibilities and general activities as drug safety and pharmacovigilance professionals.

BY MS. SCULLION:

Q. Okay. So let's look now, I think you also mentioned Section 3.2.4.2. That's on page 21 at the bottom, which speaks to appropriate and responsible selling of Opana ER.

This section, 3.2.4.2 speaks to training the sales force with respect to their obligations, correct?

A. Yes, that's correct.

Q. Okay. And that's along the lines of what we discussed before about the sales force, if they saw hallmarks of a pill mill and reporting it up, correct?

A. Yes. And, again, I referred to a form that was in routine use to make that communication happen.

Q. Is there anything else in RiskMAP that -- that reflects a policy or procedure at Endo to monitor for pill mills with respect to Opana ER, other than what we just discussed?

MR. LIMBACHER: Object to form. Object to the extent it falls outside of the scope of the topics on which he's designated.

Take your time and review the document.

THE WITNESS: What I would say is that the entirety of the RiskMAP was put into place to mitigate and prevent abuse and misuse, right, all of the topics here, whether they be related to education, physicians, patients, sales representatives, distribution chain, tamper-resistant prescription pads, pharmacovigilance, drug safety monitoring and others, but I think I've pointed you to what for me are the most specific selling points where we would be most like -- the company would have been most likely to see evidence that --

of a suspected pill mill activity.

BY MS. SCULLION:

Q. Okay. The -- Endo had access to information that told it the number of prescriptions for Opana ER that any given physician within a call plan was writing in a specific period of time, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: From time to time the company did subscribe to certain audited prescription level information at the pharmacy level. IMS is usually one of the customary companies, and I point out that it is -- it's imprecise, but it gives as close as available information on that. Imprecise being that not all pharmacies report, not all distributors have consistent reporting. So, you know, to some extent it's indexed information, but it gives us -- from time to time we did subscribe to that information to get an idea for the sales force on targeting and other purposes, physician use.

BY MS. SCULLION:

Q. Right. So, for example, Endo made use of -- let me back up.

You said IMS was one source of that data?

A. Correct.

Q. Certain point in time, Wolters Kluwer was also a source of that data, correct?

A. I think so. In fact, they're referred to in here. We changed vendors once or twice, I believe.

Q. Regardless of the particular vendor, Endo used that information about prescriptions written by specific healthcare providers to, as you said, set -- help set sales goals, right?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. For individual reps?

A. Not necessarily at the individual prescriber level, but we certainly would have used that audited or that prescription data to help set general sales goals.

Q. Okay. Did Endo use that

information to designate deciles within which different healthcare providers fell to assist in prioritizing sales force allocation?

MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics on which he's been designated.

THE WITNESS: Is this 30(b)(6) or is this --

BY MS. SCULLION:

Q. This is fine in your personal capacity.

A. Okay. From time to time that was a practice. It wasn't always used. It depended on the importance of the product, but, yes, sometimes physicians were deciled. It also is important in that it allowed us to understand whether or not a given physician was an experienced prescriber of pain medicines.

We -- best of my recollection, that was an important component of the targeting, where we sent our sales representatives. The physicians had to be experienced pain specialists or internal

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medicine physicians that had a subspecialty in pain, for the most part. So that deciling activity helped us to confirm that.

Q. Okay. So the deciling activity, though, was based, for example, on the IMS or Wolters Kluwer data, correct?

A. Across all -- you know, whatever the basket of competing products was, not necessarily specific to any one of our products.

Q. You did have information, like you could get on a weekly or monthly to see how sales of Opana ER were doing, correct?

A. Not always at the physician level, but, yes, we had prescriptions, either IMS or Wolters Kluwer or whomever else that gave us, if we chose to subscribe to it at that moment, weekly or monthly prescriptions. We didn't always purchase that information for every product and every physician, so I wanted to make that distinction.

Q. Okay. So, for example, from time to time reports would be circulated that would show specifically the top 50 prescribers for Opana ER?

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A. I don't necessarily recall that, but if you've got something I can look at to refresh my memory on that. You look like you do.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 8.)

BY MS. SCULLION:

Q. Hand you what's been marked as Exhibit Number 8. Exhibit Number 8 is Bates stamped ENDO-OPIOID_MDL-00869053, and we've marked it in the upper right-hand corner, E1175.

Mr. Lortie, do you see Exhibit Number 8 is an e-mail from Larry Romaine to David Kerr and others in September of 2007?

A. Yes. I'm not -- I'm not one of those others because I wasn't there at this point, but I see that, yeah.

Q. And you see the subject matter is "Opana Top 50 Writers"?

A. Yes, I read that.

Q. Okay. And then if you'll turn to the attachment to the e-mail, which begins at E1175.5, you'll see it's a chart headed "Top 50

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Opana ER Writers." This first page is labeled "Spec I," which I understand to be specialty one for a period January '07 through July '07.

Do you see that?

MR. LIMBACHER: Object to form, object to questioning him in his capacity as a fact witness regarding a document that was created before he became employed at the company.

BY MS. SCULLION:

Q. So I understand the document was created before you were employed, but I just want to show you that this is -- strike that.

If you look on E1175.5, you see it lists detailed information about individual prescribers listed by name and address, correct?

A. Yes, I see that.

Q. And it shows their monthly sales, correct?

A. It appears to show that, yes.

Q. Right.

And then it shows on the left-hand column the sales representative associated with that prescriber, correct?

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A. Yes, I see a column titled "Rep Name," so I guess that's what that is.

Q. And the district manager as well associated with that rep then?

A. Correct.

Q. And so fair to say that Endo did have access to detailed information about the sales of Opana ER for any given prescriber that its sales reps were calling on, correct?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: During January '07 and July '07, that's what this shows us, yes.

BY MS. SCULLION:

Q. And you saw similar information at other points in time when you were employed by Endo, correct?

A. I think as I testified a minute or two ago, I don't recall the top 50 list being circulated, but I came in after the product had been launched. It could have been this is an early launch activity. I'm not sure.

Q. Do you recall seeing similar

level of detail of information about any product sales in terms of individual prescribers' monthly sales? Do you recall seeing that kind of information?

MR. LIMBACHER: Object to the form.

THE WITNESS: Sitting here right now, I don't, but I haven't thought about this for quite a while. We certainly had access to prescriptions, but how it was represented from time to time, it's -- you know, there would have been specific instances, but this one I hadn't seen before.

BY MS. SCULLION:

Q. Are you aware of anyone -- put your corporate representative hat back on.

A. Okay.

Q. Did Endo have any procedure whereby anyone monitored the sales numbers for let's just say -- let's start with an individual sales territory, not individual physicians, but just sales territory, looked at sales numbers and sales territories to assess whether there

was any unusual pattern of prescriptions for Opana ER?

MR. LIMBACHER: Object to the extent it falls outside of the scope of the topics on which he's been designated.

BY MS. SCULLION:

Q. To be clear, I'm asking as part of any anti-diversion efforts, did Endo have any process to examine prescription levels on a territory basis to look for unusual patterns?

A. Endo certainly had policies and procedures to, as you said before, measure prescriptions for its products. What we sometimes had view of is competing products as well. To the extent that that was used as part of an abuse and diversion mitigation process, I don't recall specifically, but I'm happy to look at something.

Q. Sitting here as Endo's corporate representative, are you aware of Endo having any procedure as part of its anti-diversion efforts whereby someone would monitor levels of prescriptions for Opana ER to see if there's an

unusual pattern that might indicate, for example, a pill mill?

MR. LIMBACHER: Object to form.

THE WITNESS: Well, I think that generally in the context of the RiskMAP and the REMS and the ADD activities, that would fall under general activities that if something jumped out at someone that was seeing it, they would have had a channel to report it or discuss it. Whether or not that's memorialized in any of those documents, I'm not sure, but I will say that if somebody had reason to believe that our products were being abused or diverted from any source, they all knew that they had an obligation to report it up through the channels, legal, compliance, their sales leadership or whatever function they were.

Whether or not that's a specific written policy, I would have to go back and do some work, but for me it falls under the general compliance employee

code of conduct that every employee of the company, whether or not it was involved in the sales force or any other aspect, had signed on to. Somebody saw something that didn't look right, they would report it, and they would report it to the appropriate people who would then investigate it.

BY MS. SCULLION:

Q. So the question is as part of its anti-diversion policies and procedures, did Endo have anyone who was specifically tasked with going in affirmatively, proactively to look at sales data to see if it could detect any unusual patterns that may be indicative of a pill mill?

MR. LIMBACHER: Object to form, asked and answered.

THE WITNESS: I would give the same answer. I think that under the employee code of conduct and then further on under the compliance agreement and the certification and the training that every employee at the company had to undertake, everyone knew

that whether that was a signal or any other signal of inappropriate use of any of our products, they would know what to do about that and that would be to report it to somebody above them, so that's my answer to that. I think that was a well-controlled process that falls into the overall objectives of the company.

BY MS. SCULLION:

Q. But the answer is no, it was not anyone's specific job to proactively go in and monitor, let's say, on a monthly basis sales data to see if it could detect any unusual patterns that may be indicative of a pill mill, that was not anyone's specific task to do that, correct?

MR. LIMBACHER: Object to form, misstates his testimony.

THE WITNESS: And my answer is I'm not sure, but in the context of the RiskMAP and the REMS and other activities, there were activities that encompassed that and we spoke about many

of them. If a sales rep saw prescriptions being paid for in cash, saw law enforcement presence, doses being prescribed without being individualized to a given patient, frequency of prescriptions to replace lost medications, and there were 10 or 12 things here that the sales representatives and managers were trained on. So I would say that that's directly related to your question, but -- and that's -- you know, that's such an important underpinning of the company's policy in that area, to watch out for signs of inappropriate use, abuse, diversion of its products.

BY MS. SCULLION:

Q. What you just described is a passive process of if someone happens to see something, if a sales rep happens to see something, if someone happens to see a media report, there was a certain obligation to report it up.

What I'm asking was there any

process as part of Endo's anti-diversion efforts to proactively, actively go in and look for signs of pill mills, for example, by monitoring sales data? There was no active process, was there?

MR. LIMBACHER: Object to form, misstates his testimony, asked and answered.

THE WITNESS: Yeah, I'd have to go back, but, again, we spoke about several active activities. We outlined them when we began this discussion, the internet monitoring, the Inflexxion monitoring, the drug safety pharmacovigilance, the reporting process by which our sales reps were trained and required to report things that they saw and came upon, so I think for me all of that, plus the employee code of conduct says that if somebody, through whatever activity, whether actively, which could have been, I just don't recall, or passively in other monitoring of prescriptions to see an anomaly,

something that looked unusual, every employee in the company knew exactly what to do with that information, that would be to report it to compliance, legal for follow-up.

BY MS. SCULLION:

Q. So, for example, did Endo have any algorithm that it used and applied to the sales data that it was looking for for other purposes, did it have any algorithm to apply to that sales data to see if there was an unusual pattern that may be indicative of a pill mill? Did it do that?

MR. LIMBACHER: Object to form.

THE WITNESS: I don't recall any algorithms looking for anything specific in the sales data. We had professionals whose job it was to validate the sales data, the prescription data for its many uses, but I don't recall a specific algorithm being used for any of those things.

BY MS. SCULLION:

Q. Did Endo ever have a policy as

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part of its anti-diversion efforts by which sales reps were to actively go out and ask healthcare providers they were calling on whether those healthcare providers had suspicions about any pill mills that may exist in the territory that that sales rep served?

MR. LIMBACHER: Object to form.

THE WITNESS: No, absolutely not. That would have been inappropriate. Our sales reps were trained as sales representatives, not as law enforcement agents.

BY MS. SCULLION:

Q. Well, did -- was it anyone's job within Endo to survey the healthcare professionals in whom it was calling to see if those healthcare professionals had suspicions or knowledge of pill mills in their areas?

MR. LIMBACHER: Object to form.

THE WITNESS: Oh, I would say, yes, in terms of a follow-up of a specific instance. Again, as I hopefully explained, any time suspicion was raised through the appropriate

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channels, a compliance officer, a member of the legal department would follow through, and that sometimes encompassed discussions with law enforcement, with physicians, with office staff. So, yes, those investigations did encompass exactly what you just said.

BY MS. SCULLION:

Q. And those were investigations after someone had already noticed something and a sales rep or other Endo employee had noticed something either in the field or in the media or otherwise and reported it, right?

A. I'm not aware of us investigating something that hadn't been raised to the level of an investigation being required.

Q. Was it anyone's job at Endo to go out proactively, before sales reps were calling on a healthcare provider to determine whether that healthcare provider might be a pill mill?

MR. LIMBACHER: Object to form, object to the extent it falls outside the scope of the topics on which he has been designated, asked and answered, and

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we're well past 12:30 at this point, counsel.

THE WITNESS: The -- before anyone was put on the active call list, they had to satisfy certain requirements, licensed physician, experienced in pain medicines, and I'm speaking again to Opana ER promotion, obviously licensed by the DEA, just important to put on the record that not all licensed physicians are able to write or prescribe for controlled substances. There are specific requirements and monitoring licensure and monitoring of that by DEA. So before anyone was allowed to be on the call list, they had to satisfy all of those criteria.

And then, as we've testified before, if in the course of calling on them, whether the first time they walk through the door or years after, our sales representatives noticed any aberrant behavior, anomalies that line

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up to the topics that we just spoke about, they had policies and procedures that are in writing, trained, certified that they would follow.

BY MS. SCULLION:

Q. So the answer is no, in order for a physician to be on the call list, no one went out first and did any due diligence, any office visits to see whether that healthcare provider might, in fact, be a pill mill, right? That wasn't done before they were placed on the call list?

MR. LIMBACHER: Same objections.

THE WITNESS: I think I've answered the question.

BY MS. SCULLION:

Q. So the answer is no, that did not happen?

A. I'm not aware of that happening.

MS. SCULLION: Okay. We can stop here for lunch.

MR. LIMBACHER: Thank you.

THE VIDEOGRAPHER: Going off the record at 12:38 p.m.

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(Luncheon recess.)
THE VIDEOGRAPHER: We are back on the record at 1:19.
BY MS. SCULLION:
Q. Welcome back, Mr. Lortie. You understand you're still under oath, correct?
A. Of course, yes.
Q. Thank you.
Before lunch we were discussing the process for monitoring for pill mills. One of the things that you testified to was that reps could report on a suspected pill mill, and if it was corroborated, the pill mill would be removed from the rep's call plan, correct?
A. Yeah, and just for clarification, I mean pill mill is the term you're using there. I don't think that's represented in our documentation, but any evidence that the representative saw in his or her activities that suggested that that healthcare practitioner or physician's office was involved in inappropriate activities would lead to the set of activities that we spoke about.
Q. And so among the -- I think we

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talked about the hallmarks that a rep would be trained to look for would include, for example, suspiciously high numbers of prescriptions given the size of the office, just a high number of patients, lines out the door, those kind of things, right?
A. I'm going to refer to the report so that I can accurately answer your question.
Q. Sure. Which report are you looking at?
A. So this is the report of suspected diversion, which was the form by which the sales representative would have submitted their concern.
Q. If you could hold one moment because I --
MS. SCULLION: Do we have the report?
BY MS. SCULLION:
Q. I apologize. Could you read into the record the numbers in the bottom there.
A. Yes. So what I'm referring to is titled ENDO-OPIOID_MDL-02148238.
Q. Okay. And we're going to put an

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exhibit sticker on that one and make a copy at the break, so we're going to mark that as Exhibit Number 10.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 10.)
THE WITNESS: So on this form, this again is the form by which a sales representative would report suspected signs of a suspected diversion, includes a large proportion of prescriptions paid for in cash, drugs and doses being prescribed are not individualized, lack of qualified office staff present, such as RNs or nurse practitioners, special entrance requirements to the practice and/or lack of signage, large distances between the doctor, patients and pharmacy, high frequency of prescriptions to replace lost prescriptions or medications, managed care organization excluded this doctor from writing prescriptions, law enforcement presence in or around the

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office, prescriber told you personally that he or she is no longer able to prescribe scheduled products and then there's an other, which, of course, allowed the sales representative to input whatever it was that caused them concern.
Q. Okay. And to be clear, all these questions are in your 30(b)(6) capacity?
A. Okay.
Q. Or representative capacity.
And let me hand you what's been marked as Exhibit 9.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 9.)
BY MS. SCULLION:
Q. I'll hand you what's been marked as Exhibit Number 9. And Exhibit Number 9 is Bates stamped ENDO-OPIOID_MDL-02924490, and we have stamped it in the upper right-hand corner E1247.
And, Mr. Lortie, if you could turn to page E1247.5, which is the last of the

ordinary size, eight and a half by 11 size pages?

A. Okay.

Q. And this page is an instruction and guidelines tab for what we understand to be the Excel spreadsheet that is encompassed in Exhibit Number 9, and it describes in the -- in that gray box at the top, the RBD prescriber removal process.

Do you see that?

A. I do, yes.

Q. Do you understand that to refer to the regional business director prescriber removal process?

A. Yes.

Q. And as part of that removal process, if you go down to the "Criteria/Guidelines within your district" it says in the second bullet point, "Suspicion of diversion should continue to be submitted to Corporate Compliance for investigation and removed through that process."

Do you see that?

A. Yes, I do.

Q. Okay. And does that refer to the process you've just described of reporting up suspected diversion for confirmation by corporate compliance?

A. Yes, I believe that does.

Q. Okay. And then if you look on page E 1247.7, which is the first of the large spreadsheet pages, you'll see in the right-hand column -- sorry, various codes used. For example, you see new IMS reason code. I think these are all reason code it says retired, no access, retired, no access, compliance.

Do you see those reason codes?

A. Yeah, I actually see two columns with reason codes. Apparently, there was an Endo reason code and an IMS reason code, and I'm not sure what the difference is between them.

Q. Fair enough.

A. But, yes, I see the column that you're reading.

Q. Let's look on the Endo reason code column.

Do you see that?

A. Yes.

Q. Are these the reasons -- the reason codes Endo used to indicate the reasons why a prescriber was removed from a call plan?

MR. LIMBACHER: Object to form, foundation.

THE WITNESS: It's hard for me to be sure about that because I don't see anything that tells me whether this was physicians under investigation or before they had been removed or after that had taken place, but not knowing that, certainly, these are the reasons for investigation into whether or not they should be. It could -- it could be, but I just can't tell from here.

BY MS. SCULLION:

Q. I mean, so as Endo's corporate representative, do you know what the procedures were to indicate within Endo's records whether a physician had been removed from a call plan for compliance reasons for confirmation of being -- confirmation of diversion?

MR. LIMBACHER: Object to form.

THE WITNESS: Yes. I mean, I

think it's in the context of what we had spoken about this morning, as the result of suspicion being raised, and that could have been raised by a number of different ways, either sales representatives sending in a form, internet surveillance, epidemiologic drug safety surveillance, review of prescription by the risk management team. Any number of ways would all lead to the same next step, which would be investigation by compliance officer, legal department to understand whether or not there was a -- whether or not that should result in the removal of the physician from the call list or not. So there were very specific operating procedures to be followed in that case.

MS. SCULLION: Right. So move to strike.

BY MS. SCULLION:

Q. My question is do you know how it was recorded in Endo's records when a physician was removed from the call plan for reasons of

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confirmation of diversion? Do you know what the reason code would look like?

MR. LIMBACHER: Object to form. I think he answered your question. You asked him what were the procedures.

THE WITNESS: I was trying to answer the procedures question, but your question is do I know -- I believe that would have been titled compliance as opposed to retired, which is sort of self-explained, if somebody had died obviously. No access often shows up because the health system prohibits access by sales representatives to healthcare practitioners.

So I think the answer is -- my understanding is the answer is compliance in that case.

BY MS. SCULLION:

Q. Okay. So if a healthcare provider had been reported up and confirmed to be engaged in diversion, they would have been listed -- reason code listed would have said compliance for removal from the call plan,

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right?

A. If it was listed as compliance on a list of confirmed removals, and what I was trying to point out before is that this may be work in progress. So listing of compliance could be this person is under investigation or the investigation is complete and they've been removed. I just can't tell if that's what this spreadsheet is telling us or not.

Q. Okay. But if they were removed eventually on a final exclusion list, it would list compliance as the reason code for that removal, right?

A. I believe that's correct.

Q. Okay. Now, again, all within your corporate representative capacity, if a provider that was engaged in diversion were on a call rep's -- sorry -- a sales rep's call list and had not yet been removed from the call list for suspected diversion -- strike that.

If a provider was on the call list and was engaged in diversion but was never reported up as being engaged in diversion, would the sales rep be getting credits for the

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prescriptions written by that provider?

MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics on which he has been designated.

THE WITNESS: I would hope that in the vast majority of cases that anyone exhibiting the activities or the signs and symptoms of being a pill mill, to use your word, would be reported. I'm not sure whether there were -- we're certainly not aware of any cases where somebody was diverting drugs and doing inappropriate activities related to opioids that wasn't reported.

But if we were unaware, and by "we" I mean any member of the company, sales rep, sales leadership, compliance, law enforcement, if no one was aware, then that physician would continue to be on the call list. I'm not aware of cases like that, but that would be -- you know, in the absence of them being removed as the result of an

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investigation, they would be on the list, I guess.

BY MS. SCULLION:

Q. Well, certainly, you are aware of instances in which the only way it came to Endo's attention that there was a pill mill on the call list was after the doctor was arrested and, for example, it was reported in the media, right; that happened?

A. I'm not sure of any specific instance where that was the only way we found out. That was one of the ways that we did our best to keep our pulse on the -- our fingers on the pulse of what was happening, but I'm not sure, you know, it's an issue of timing.

Q. You're not saying that the Endo -- that Endo's sales reps reported up every pill mill that was on their call list, are you?

MR. LIMBACHER: Object to form.

THE WITNESS: Oh, I'm absolutely saying that. To the extent that any of our employees knew there were those activities underway, they would have reported it 100% of the time.

BY MS. SCULLION:
Q. And had Endo audited its process to make sure that sales reps had caught every single pill mill that was on their sales list and reported it up?
MR. LIMBACHER: Object to form, misstates his testimony.
THE WITNESS: I'm not sure what you mean by "audited." We had a complete set of responsibilities and activities that are outlined in the RiskMAP and the REMS and other documents, code of conduct for every employee, specific activities all intended to mitigate the chances of that happening. So -- and a risk management committee that, I suppose, is fair to say served an audit capacity in that they were monitoring prescriptions and monitoring all those activities and ensuring that those steps were being taken, a compliance officer in a compliance department who had the same obligation that's reported directly up

to the board. So I would say, yes, Endo did put into place a rigorous program and had audit in -- internal auditing in place to make sure that that was, to the best of its ability, doing the job that needed to be done.
BY MS. SCULLION:
Q. Did Endo ever investigate -- strike that.
To the extent that Endo learned of a pill mill on its call lists through a media report and not through a sales rep report using the form that you spoke of, did Endo have a policy to go in and investigate why that pill mill had not been reported up earlier?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm not aware of the extent to which that was part of the policy. Remember, it's -- rather, it's important to just clarify that our reps were not in any physician's office every single day. They called on them a couple weeks, maybe a month, probably that kind of a frequency. So to the

extent that they would be depended on, outside of the normal course of their activity, to be the first to notice something, I think it's probably unreasonable to expect that.
That being said, any time the sales rep or the compliance officer within our policies and procedures were made aware of something that raised suspicions, all of the things we talked about earlier were put into motion.
BY MS. SCULLION:
Q. So the answer is no, Endo did not have a policy to go back and investigate why a pill mill had not been picked up --
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. -- if it learned about that pill mill other than through a sales rep report, right?
MR. LIMBACHER: Object to form.
THE WITNESS: No, I'm sorry, I'm not going to agree with that. Endo had an entirety of policies, procedures and

people whose entire job was to mitigate abuse and diversion according to the RiskMAP and the REMS and the ADD, and within the context of that, those activities, when signaled, were followed up on.
BY MS. SCULLION:
Q. Sorry. The question was did Endo have a policy to investigate why a pill mill had not been reported up if Endo only learned of a pill mill through a media report, for example?
MR. LIMBACHER: Object to form, asked and answered.
THE WITNESS: Yeah, I'm not aware that there was a specific policy to address that. We felt very comfortable that by following the rules and regulations that we were doing our part to mitigate the abuse.
BY MS. SCULLION:
Q. And with respect to a sales rep reporting up a pill mill, you agree it's possible that a sales rep might decide it wasn't in their best interest to report a pill mill if

the sales rep thought that might negatively impact their compensation based on sales in their territory, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: No, absolutely disagree with that.

BY MS. SCULLION:

Q. And why is that?

A. Because the sales reps were very well aware that, ultimately, if that was an activity they undertook for that reason, they'd be terminated.

Q. If they were caught?

A. We had pretty solid policies and procedures that I think ensured that they would be caught.

Q. But those policies and procedures didn't include, for example, going in and investigating if, in fact, a sales rep hadn't reported up a pill mill that Endo learned of only through the media? You never went back to see, well, hey, why didn't the sales rep actually report up that pill mill?

MR. LIMBACHER: Object to form.

THE WITNESS: Could very well be that the representative or the manager was interviewed, in fact, I would be surprised if that didn't happen, but every activity related to this doesn't require a standard operating procedure. It's why we have employee code of conduct, so that everybody understands the overarching objections -- objectives, my mistake -- overarching objectives of what we're trying to accomplish here, and that is be responsible and not allow abuse and diversion of controlled substances.

So every single activity doesn't require a written policy when you've got a guidance document and people whose entire job is to make sure that the company is fulfilling its obligations.

BY MS. SCULLION:

Q. So you wouldn't agree, for example, that a sales rep might decide to play the system and delay reporting up a suspected pill mill in order to avoid negatively impacting

their compensation?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. That would never happen?

MR. LIMBACHER: Object to form.

THE WITNESS: In my experience, that would never happen.

BY MS. SCULLION:

Q. Did Endo have any policies to ensure that sales reps' compensation was not negatively impacted by the pill mill reporting and investigation process?

MR. LIMBACHER: Object to form.

THE WITNESS: The policy was that if a given practitioner was identified as possibly being involved in abuse and diversion that they were removed from the call list. They would -- their prescriptions and relative business would have also been removed from the target for the representative and the manager and the regional manager as well, all being done to not have a negative impact on someone's --

someone's earning potential.

BY MS. SCULLION:

Q. But that wasn't always the case, right? There were times when a prescriber was removed from a call list and it was -- and the adjustments to compensation were not made retroactive for the period of the investigation of the report, right?

MR. LIMBACHER: Object to form.

THE WITNESS: While the investigation was underway, the physician remained on the call list.

BY MS. SCULLION:

Q. So while a physician was under investigation for being a potential pill mill, was the rep expected to continue to call on the physician?

A. No, but they weren't removed until the investigation had been complete.

Q. And so during that time, when the investigation is ongoing, the rep is still being expected to meet a sales goal based on having that physician's prescriptions be part of their call plan, right?

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MR. LIMBACHER: Object to form.
THE WITNESS: No. Actually, that's not correct. The -- there was a general policy for correcting things like that retroactively, and it was a program that involved sales operations, sales leadership, to go back and make necessary adjustments to deal with situations like that.
BY MS. SCULLION:
Q. But that -- those were discretionary adjustments, correct?
A. They were, but they were part of standard policy, standard approach.
Q. They were discretionary, they didn't always happen, right, those adjustments?
A. I think they happened as a matter of practice.
Q. Do you think sales reps understood that it would always happen?
A. Yeah, I do, because they knew we would always endeavor to be fair to them and not penalize them for the missed activity or the inappropriate activities of their customers. We

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wanted them to know that we expected them to raise their hand and flag these activities, and we didn't want that to be a financial burden on them.
Q. And so, certainly, if that discretion was not exercised in their favor and they were given instead of compensation just Endo points, that would not be consistent with sending the reps a message of you should report and don't worry, you're not -- compensation is not going to be affected, right?
MR. LIMBACHER: Object to form, objection to the extent this falls outside the scope of the topics on which he's been designated.
THE WITNESS: Yeah, I'm not sure I understand your question. Sorry.
MS. SCULLION: Sure. Let's look at some documents. Can I have E1599, 1600 and 1601.
MR. LIMBACHER: Are these questions in his capacity as a fact witness or as a 30(b)(6) witness?
MS. SCULLION: These are

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30(b)(6).
MR. LIMBACHER: I'm sorry?
MS. SCULLION: These are 30(b)(6).
MR. LIMBACHER: I object to the extent they fall outside the scope of the topics on which he has been designated.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 11.)
BY MS. SCULLION:
Q. Mr. Lortie, let me hand you Exhibit Number 11, and that is Bates stamped ENDO-OR-CID-00408959. Upper right-hand corner we've marked it E1599.
And --
A. I'll just take a look, if it's okay.
Q. Sure.
A. (Witness reviews document.)
Thank you. I've looked it over.
Q. You've looked over Exhibit Number 11.

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You see that Exhibit Number 11 is a series of e-mails concerning removing a physician doctor, Winthrop Risk from the call list for two sales reps, Kris Baerenwald and Jodi Yeggy and then also how to adjust their compensation following that removal?
A. I see Kris Baerenwald. I didn't see the second sales rep.
Q. Sure. If you look on the very first page.
A. The top page?
Q. Yeah, the very first page, E1599.1 --
A. Oh, yes, thank you, yep.
Q. That's a good point, E1599.1 you see in the middle of that page that e-mail from Dennis Breakstone to Demir Bingol?
A. I do, I see Jodi Yeggy, yep.
Q. Okay. And if you'll go to the bottom of E 1599.1, there's an e-mail from Colleen Craven to Demir Bingol and Dennis Breakstone dated October 15th, 2009. That carries over to E1599.2.
Do you see that?

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A. Yes, I do.
Q. And Ms. Craven was head of compliance, correct?
A. She was the chief compliance officer at this time, yes.
Q. So, certainly, her knowledge and understanding of the policies with respect to adjusting compensation in connection with removal of a physician from the call list by compliance, you would expect her to know what she's talking about, right?
MR. LIMBACHER: Object to form.
THE WITNESS: With respect to the removal and the rules and regulations, as she outlines here in some detail, absolutely. I'm not sure the extent to which she would have been involved in the compensatory part of this specifically, but she was certainly as in her role as chief compliance officer responsible for making sure that the policies were appropriately executed.
BY MS. SCULLION:
Q. And if you look at her e-mail,

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she says she provides a brief explanation of when the corporate compliance department determines removal from the call plan.
And she explains that "When the Corporate Compliance determines that there is enough evidence to remove a prescriber from the call plan, the effective date is the date of the physician and rarely retroactive," correct?
A. I see that, yes.
Q. Okay. So, again, the removal is not retroactive to remove them from the call plan for -- as of the time the sales rep, for example, reported the prescriber.
That's what she's saying, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: That's what she's saying.
BY MS. SCULLION:
Q. Okay. And that's your understanding of what the policy was, correct?
A. Yes. My understanding is that they -- their name was not removed from the call plan until the completion of the -- whatever

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investigation was undertaken.
Q. And then when it was removed at the completion of the investigation, it was not retro -- made retroactive, correct, removal?
A. Correct.
Q. Okay. And then in responding to concerns raised by Dennis Breakstone about how this removal -- strike that -- about how the investigation period for this prescriber impacts these representatives' compensation, Ms. Craven says, "I do understand Dennis's concerns; however, it is my understanding that sales management has a way of making such situations equitable. I suggest that you speak with either Maria or other RDs."
Do you see that?
A. I do, yes.
Q. So she's referring over to a process to make things equitable but not a firm process to retroactively adjust, right?
MR. LIMBACHER: Object to form.
THE WITNESS: I think she's referring to the way that those adjustments would be made in the normal

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course of business, yes.
BY MS. SCULLION:
Q. Now, if you look on the first page, E1599.1, you see then Mr. Breakstone writes to Demir Bingol and says, we agreed to look into getting additional discretionary bonus dollars for these two reps due to their decline in Opana ER business as a result of Dr. Winthrop Risk, correct?
A. Correct.
Q. So this is looking at it for discretionary adjustment to their compensation, correct?
A. Correct.
Q. And Mr. Bingol responds, "the discretionary period is forthcoming," and he is going to take action, right?
A. Yes, that's what he says.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 12.)
BY MS. SCULLION:
Q. Okay. Hand you what's been marked Exhibit Number 12, and Number 12 is Bates

stamped ENDO-OPIOID_MDL-02098725, and we've stamped it E1600.1.

And this is at the top of 1600.1 an e-mail from Demir Bingol to Ronda Wells attaching the corrective action requests for the midwest. And if you look to pages E1600.2 and 1600.3, you'll see Mr. Bingol is requesting a discretionary bonus for the two reps, Jodi Yeggy and Kris Baerenwald based on their lost ability to have called on Dr. Winthrop Risk.

Do you see that?

MR. LIMBACHER: Object to form.

THE WITNESS: So what's the -- I mean, I see the two forms that you're referring to, yes.

BY MS. SCULLION:

Q. Okay. And this is a prelude then to the next document. I just want to make sure you saw the chain of events here.

And then let's look at Exhibit Number 13.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 13.)

THE WITNESS: Let me just finish with this one.

MS. SCULLION: Sure.

THE WITNESS: I'll take that, but I'm going to look at it in a second.

(Witness reviews document.)

MS. SCULLION: And for the record, Exhibit Number 13 is Bates stamped ENDO-OPIOID_MDL-02182533.

MR. LIMBACHER: Again, note my objection to this series of questions to the extent it falls outside the scope of the topics on which he's been designated.

BY MS. SCULLION:

Q. And, Mr. Lortie, do you see that Exhibit 13 is Demir Bingol now writing back to Dennis Breakstone and saying, "Unfortunately, none of the Corrective Action requests were granted for your folks." And he attaches, again, the corrective action request for Jodi Yeggy and Kris Baerenwald with respect to their lost ability to call on Dr. Winthrop Risk. That's on pages 1601.3 and 1601.4.

So is this an example of reps not getting any discretionary adjustment to their compensation, despite having done the right thing?

MR. LIMBACHER: Object to form and, again, object to the extent it falls outside the scope of the topics on which he's been designated.

THE WITNESS: I mean, I don't think you can draw that conclusion. What we see here is the outcome of a process that was -- I can attest was followed regularly, but for some reason, and it's not clear in the documentation that you provided, those corrective action requests were not granted, they were given some discretionary points as part of that, but I don't know any more about this.

What I can say, though, is that our sales reps, whether for Opana or for other products, whether in 2010 or years before and after generally knew that sales management would be fair and

equitable in making adjustments for anomalies in any number of things that could impact their incentive comp.

BY MS. SCULLION:

Q. I mean, do you think that these sales reps felt that they had been treated fairly and equitably, having not been able to call on a doctor that they had reported up and then not getting any discretionary compensation, just getting Endo points? You think that was a message that was sent to them?

MR. LIMBACHER: Object to form.

THE WITNESS: You asked me two questions there. I don't know how those sales reps thought. If you would like an answer to that, you would have to ask them.

BY MS. SCULLION:

Q. Looking at this from a manager's standpoint, do you think this is sending the right message to these sales reps?

MR. LIMBACHER: Object to the form and foundation.

THE WITNESS: I would suggest

that knowing how Endo approached these situations, that there was very likely to be a solid reason for why those were not approved. It's not evident by the documentation you've given me here, and that based on that, there would have been a very solid answer for these two representatives, and I would suspect that they would have understood and taken that into consideration and moved on.

BY MS. SCULLION:

Q. When you say there'd be a solid reason, it's not documented by Mr. Bingol, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: In this e-mail, it's not, no.

BY MS. SCULLION:

Q. Right. And, again, that's the nature, though, of a discretionary bonus is it may or may not be granted, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Correct.

BY MS. SCULLION:

Q. So the policy was that reps on a discretionary basis might have their compensation adjusted, but it was not guaranteed, right?

MR. LIMBACHER: Object to form.

THE WITNESS: There was a policy in place that included all of the people that had relevant information and decisions were made.

BY MS. SCULLION:

Q. And that process did not include a guarantee that reps' compensation would be adjusted if they, in fact, reported up a doctor they suspected of engaging in diversion, right?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm sorry. I can't agree with that the way you formulated it.

What I would say is that the policy for making adjustments to sales representative's incentive comp, whether it's for the very specific reason that you've raised here or any number of

reasons, physicians who move, practices that close, new practices that show up, there was a -- and I would -- I would certainly testify very comfortably that our representatives knew that sales management would do the right thing and in those circumstances. With regards to this particular instance that you put in front of me, I don't have enough information to make a call on it.

BY MS. SCULLION:

Q. And the question is very simple.

The policy, though, did not guarantee that a sales rep that reported up a prescriber on their call list as potentially engaged in diversion would, in fact, have their compensation adjusted to make up for their loss during the investigation period, right?

MR. LIMBACHER: Object to form and object to the extent it falls outside the scope of the topics for which he is designated.

BY MS. SCULLION:

Q. It wasn't guaranteed?

A. That's a statement, not a question.

Q. Is that correct; it was not guaranteed?

MR. LIMBACHER: Object to form, same objections.

THE WITNESS: The policy and the approach to this on the part of sales management was to look at each case based on its own merits and make the necessary adjustments.

It was by definition a discretionary policy, but our sales representatives knew that, for whatever reason, if it was fair, the sales rep -- they would be taken care of in an equitable manner.

BY MS. SCULLION:

Q. And do you see if you look back at Exhibit Number 11, going to page E1599.7, you see that Kristeen Baerenwald reported up this doctor as being no longer allowed to write Schedule II medications because the state of Iowa had suspended his ability to write

scheduled medication for five years, reported that up on August -- in August of 2009.

Do you see that?

A. Yes, I do.

Q. And the final decision on whether Kris Baerenwald would get any compensation to make up for her loss during the investigation of Dr. Winthrop Risk was not until April of 2010, months later, right? That's in Exhibit 13.

A. Just flipping between exhibits.

Q. Sure.

A. Yeah, you're right. It looks like April 2010.

I do want to point out something that you said that turned out to be factually incorrect or something that the sales representative and I would suspect that looking through this, which is a relatively complicated investigation, and I do see that our compliance officer clarified subsequent to the original flag that, in fact, the physician's license was not revoked but that he had agreed to limit, so and it's an important distinction.

Again, I don't know the details

of this particular investigation. You had sales management, the chief compliance officer spending several months in an attempt to get to the bottom of it, and, ultimately, at the end, for reasons that are unclear here, determined that the discretionary bonus could not be awarded. That's all I can draw from this.

Q. Right.

So if you go back to Exhibit 12, and this is Mr. Bingol's corrective action request, looking at page 1600, E1600.2, Mr. Bingol states in the box labeled "Justification for IC Corrective Action, Opana ER target (Dr. Winthrop Risk) lost ability to prescribe LOA" -- long-acting opioids -- "in July 2009 and rep was told to stop promoting Opana ER."

Did I read that correctly?

A. Yes.

Q. So this rep, regardless of what the circumstances were of the investigation, was told to stop promoting to this doctor, and yet they did not get the lost prescriptions -- sorry, the lost call plan credits made up to

them in a discretionary bonus, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Right. This tells me the rep was told to stop calling and the component of their incentive, their incentive bonus, which is on top of their salary was -- was the incentive that was at -- in question here and that they were not ultimately paid that.

This is not a rep not getting paid. I think it's important to point out.

BY MS. SCULLION:

Q. This is -- the rep got points instead of cash, though, right?

A. The rep gets salary, in addition to that quarterly or regular bonuses, I can't remember if they were quarterly or monthly at that period.

In this particular case, they were given some points to make up for the -- for the circumstances.

Q. You wouldn't dispute that for Endo's sales reps, let's look in 2010, that an

important part of their compensation was the incentive compensation that they received on top of their salary?

MR. LIMBACHER: Object to form and object to the extent -- are we still asking him questions as a 30(b)(6) witness?

MS. SCULLION: Yes.

MR. LIMBACHER: Then I would object in addition that it falls outside of the scope of the topics on which he's been designated.

THE WITNESS: So your question was was the incentive comp an important part? It was part of their compensation.

BY MS. SCULLION:

Q. It was an important part?

A. They received a salary. They received bonus based on the variable part of their compensation. They received some points. They received recognition, but it is not that these representatives didn't receive pay. I just wanted to make that distinction.

Q. Understood. But they didn't receive the pay that Mr. Bingol thought they should have gotten when he requested the discretionary bonus, right?

MR. LIMBACHER: Object to form, foundation.

THE WITNESS: Apparently, they did not receive the proposed discretionary bonus. We can't tell why they didn't. There were, I'm sure, some good reasons for that, but they did not receive that, no.

BY MS. SCULLION:

Q. Keeping your 30(b)(6) hat on, as part of its anti-diversion policies and procedures, did Endo have any procedure to actively go out and review information concerning pharmacies declining to honor prescriptions by specific physicians?

MR. LIMBACHER: Object to form.

THE WITNESS: Not that I'm aware of. In terms of active, there are, of course, a number of ways that, you know, our sales reps did call on pharmacies,

they had relationships with pharmacists, so they would have picked up on this in the course of those conversations, but we -- I'm not aware that we -- that Endo sent people out beforehand with an assumption of guilt.

BY MS. SCULLION:

Q. Would you agree that it would be a red flag of a potential -- of potential diversion if multiple pharmacies within a given community had said that they would not honor opioid prescriptions written by a specific doctor?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. That'd be an indication that that doctor should be -- is suspected of diversion?

A. I would think that that could be called a red flag, yes.

Q. Okay. Now, you said that Endo didn't have anyone actively going out and looking for those red flags, right?

MR. LIMBACHER: Object to form.

THE WITNESS: Endo did not deploy

private investigators to do activities like that, but we had a number of ways that were put into place to hopefully pick up on those things should they occur, and we've spoken about many of them already.

BY MS. SCULLION:

Q. Did Endo ever go out to purchase the data from pharmacies where they would report on physicians whose prescriptions they weren't honoring in order to -- did Endo ever buy that data in order to proactively monitor for potential pill mills?

MR. LIMBACHER: Object to form and foundation and object to the extent it falls outside the scope of the topics on which he has been designated.

BY MS. SCULLION:

Q. I'm asking this as part of its anti-diversion procedures.

A. So you're suggesting there was a database that captured whether pharmacies were flagging physicians for inappropriate prescribing.

Q. I'm asking whether there was data could be obtained?

A. I don't -- I'm not aware of such data, no.

Q. So it follows that there was no procedure as part of Endo's anti-diversion procedures to actively go out and acquire such data in order to monitor that data for the red flags we just talked about?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not aware that such data exists. It could be that it does and our people were monitoring it, but I'm not aware that that data -- I've never heard of such a database existing, no.

BY MS. SCULLION:

Q. And you're not aware of any policy or procedure Endo had to go out and acquire that data for that purpose?

MR. LIMBACHER: Object to form, foundation and to the extent it falls outside the scope of the topics on which he's been designated.

BY MS. SCULLION:
Q. I'm asking all these questions as Endo's corporate representative.
A. And I've tried to answer that. I'm not aware that that data even exists, so if I'm not aware it exists, I can't be aware of a policy to purchase it.
Q. I agree.
A. That's something I'm -- I'm trying to be clear. To the extent it exists, then that's a different question, but I'm not aware of that.
Q. Okay. And then you did note, though, that reps did call on pharmacies, at least for some period of time when Endo was selling Opana ER, correct?
A. From time to time, yes.
Q. And as part of calling on pharmacies, was it Endo's policy as part of its anti-diversion efforts, that reps should be asking the pharmacists whether the pharmacists were aware of any pill mills or had suspicions of any pill mills in the area?
MR. LIMBACHER: Object to form.

THE WITNESS: I would suspect that if a representative was suspicious of that and in doing so was in the process of having an investigation mounted, I wouldn't be surprised if they would ask a pharmacist, but it wasn't part of policy to do that.
Again, our representatives were not investigative agents, they were sales representatives, and they had a policy and procedure to follow should they see something that caused them concern.
MS. SCULLION: Can I have E142, 478 and 1007, please.
MR. LIMBACHER: Jen, are we still asking questions as a 30(b)(6) witness?
MS. SCULLION: Yes.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 14.)
BY MS. SCULLION:
Q. I hand you what's been marked as Exhibit Number 14, and Exhibit 14 is Bates

stamped ENDO-CHI_LIT-00543478, and we've stamped it in the upper right-hand corner E142.
Mr. Lortie, this is a document entitled "Percocet History, Time & Events in the News Media." It bears Endo's logo and it says on the front it's prepared by Dhaval Mavani and Jacob Gettier.
Do you know who those individuals were?
A. I do not. No, I don't recognize either of those names. I'll just take a look, if it's okay through the slides.
Q. Yeah, sure.
A. (Witness reviews document.)
MR. LIMBACHER: Jen, when this was produced, did it have the handwriting on it?
MS. SCULLION: Yes, I checked multiple times. It actually looked suspiciously like mine, but it's not.
THE WITNESS: (Witness reviews document.)
Okay. I mean, I've generally looked at it. If there's a particular

page, I'm sure you'll point me to it.
BY MS. SCULLION:
Q. Sure. Yeah, if you can go to E142.7.
You see the box in the middle of the page there that says by 2002: approximately 9.7 million individuals age 12 and up had used Percocet, Percodan or Tylox for nonmedical use at least once in their life compared to 1.9 million for OxyContin.
Do you see that?
A. Yes, I do.
Q. Any reason to dispute those numbers?
A. I have no reason to agree with them nor dispute them. I have not seen this before. It predates me by a long time and has to do with Percocet, which wasn't subject of my preparation today.
Q. Okay. And you'll see that that box it says a source to the National Survey on Drug Use and Health Report, May 2004.
It's at the bottom of the -- of page E142.7.

In devising its anti-diversion policies for opioids, did Endo take into account that Percocet, its product fell into a category of products that had been used at five times the rate of OxyContin for nonmedical purposes?

MR. LIMBACHER: Object to form and object as falling outside the scope of the topics on which he's been designated.

THE WITNESS: I don't know.

BY MS. SCULLION:

Q. Did it take into account that Percocet had been misused by children as young as 13, 14, 15 at that rate?

MR. LIMBACHER: Objection, same objections.

THE WITNESS: I wasn't there at this time in question, so I really have no basis to know what Endo took into account at that time.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 16.)

BY MS. SCULLION:

Q. Let me hand you what's been marked as Exhibit 16. And Exhibit 16 --

MR. LIMBACHER: Is there a 15?

MS. SCULLION: There will be.

BY MS. SCULLION:

Q. Exhibit 16 is Bates stamped ENDO-OPIOID_MDL-03259246, and we've marked it E478 in the upper right-hand corner.

And, again, this is produced to us in this case by Endo, and it's entitled "Percocet Death Reports (1999-2000)," and do you see that it tallies up deaths in 1999, 2000 and 2001 associated with Percocet or Endocet?

MR. LIMBACHER: Object as falling outside the scope of the topics on which he's been designated.

THE WITNESS: I do see those headings as you've described them.

BY MS. SCULLION:

Q. And Endocet was the branded generic version of Percocet that Endo also sold, correct?

A. I don't recall, to be honest. I'm sorry.

Q. When Endo was developing its anti-diversion procedures and policies for opioids, did it take into account the death tolls for Percocet and Endocet?

MR. LIMBACHER: Object as falling outside the scope of the topics on which he has been designated.

THE WITNESS: This document predates my time there by at least eight years, so I have no basis to understand what Endo took into account at that time.

BY MS. SCULLION:

Q. When Endo created the RiskMAP for Opana ER, did it take into account the history for death caused by Percocet?

MR. LIMBACHER: Same objection.

THE WITNESS: My understanding is that the RiskMAP was specifically for long-acting opioids, of which Opana ER was the one in question, also those that are being actively promoted, and that's my understanding of the foundation for the RiskMAP.

Beyond that, I don't know what Endo -- what other information Endo may or may not have taken into account.

BY MS. SCULLION:

Q. But, to your knowledge, the RiskMAP was not designed to address, for example, deaths caused by Percocet?

MR. LIMBACHER: Object to form and object as falling outside the scope of the topics on which he's been designated.

THE WITNESS: Yeah, I don't know.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 15.)

BY MS. SCULLION:

Q. Let me hand you now what's been marked as Exhibit Number 15.

Exhibit 15 is an article from Cleveland.com -- or it's just an opinion piece rather from Cleveland.com authored by Carole Rendon, and we've stamped it E1007.1, and it's dated July 13th, 2016.

And if you'll go to page E1007.2,

Ms. Rendon states four paragraphs down, "The opioid epidemic has caused an unprecedented wave of death and destruction throughout Northeast Ohio."

Did I read that correctly?

A. I'd like to look at the document first, if that's okay, quickly just to...

Q. Sure.

MR. LIMBACHER: Counsel, are we asking questions with regard to this document in his capacity as a 30(b)(6) witness?

MS. SCULLION: We are.

MR. LIMBACHER: Then I would object to all such questions as falling outside the scope of the topics on which he's been designated.

THE WITNESS: (Witness reviews document.)

Okay. Thank you. I've taken a look.

BY MS. SCULLION:

Q. Okay. So, again, if you look on

the first page E1007.1, you'll see it says posted July 13, 2016. As of that date, the anti-diversion, anti-abuse measures Endo had in place under the 2007 RiskMAP, which I think you said continued, right, those had been in place at that point for nine years, right?

MR. LIMBACHER: Object to form.

THE WITNESS: If this was a 2016 and that began in 2007, yes.

BY MS. SCULLION:

Q. And would you agree that the unprecedented wave of death and destruction in Northeast Ohio was an indication that the RiskMAP policies were ineffective in minimizing diversion and abuse?

MR. LIMBACHER: Object to form.

THE WITNESS: No.

BY MS. SCULLION:

Q. Do you dispute that there was an unprecedented wave of death and destruction throughout Northeast Ohio caused by the opioid epidemic?

A. I read that here, but I have no basis to understand whether that's true or not.

But even if it was, it's speaking of the opioid epidemic. It's not -- I don't see any mention here of an Endo product or activity on behalf of Endo so...

Q. Well, if we go to the next page, the top, Ms. Rendon goes on to state, "Doctors and patients need more education about the dangers of prescribing too many pills and prescribing them too often. The unused Vicodin and Percocet in the medicine cabinet is often the Gateway drug to heroin addiction."

Did I read that correctly?

A. Yes, I see that.

Q. Percocet is an Endo product, correct?

A. Endo is one of many manufacturers of Percocet, especially in 2016.

Q. Percocet is a brand name that only Endo sold, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: With all due respect --

MR. LIMBACHER: And object to the extent it falls outside the scope of the

topics on which he's been designated.

THE WITNESS: The use of the word Percocet is similar to the use of the word band-aid or Kleenex, so we know that Endo's supply of Percocet is a small fraction of the prescriptions of Percocet that are satisfied by any number of generic manufacturers.

I see that the author is referring to it as Percocet, but we just have no way of knowing that she's assigning responsibility to Endo-branded Percocet or any activities by the company.

BY MS. SCULLION:

Q. So Percocet could include, for example, Endocet?

MR. LIMBACHER: Object to form and foundation, object as falling outside the scope of the topics on which he's been designated.

THE WITNESS: In my opinion, what I would say is Percocet could be any number of Oxycodone APAP manufactured by

any number of generic manufacturers.
BY MS. SCULLION:
Q. In devising its anti-diversion policies and procedures for opioids, did Endo take into -- try to address the Percocet in the medicine cabinet being diverted?
MR. LIMBACHER: Object to form and object to as it falls outside the scope of the topic on which he's been designated.
THE WITNESS: As I previously testified, the RiskMAP was specifically designed for long-acting opioids, in our case Opana ER. That being said, everything from the code of conduct to general understanding of all employees was that we should all do whatever we could if faced with evidence that any medicines, whether they were ours or anybody else's were diverted or abused, but, specifically, to the extent that Endo was thinking about Percocet when the long-acting opioid RiskMAP, REMS or ADD was put together, I can't answer

that.
BY MS. SCULLION:
Q. The principles that informed Endo's anti-diversion policies and procedures for Opana ER, do those principles include what Ms. Rendon describes here as the problem with prescribing too many pain pills and prescribing them too often?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm sorry. I didn't hear the question.
BY MS. SCULLION:
Q. Sure. In terms of the principles -- are you familiar with the principles that informed Endo's policies and procedures to combat diversion and abuse of Opana ER?
A. Yes.
Q. And did those principles include what Ms. Rendon refers to here, which is the problem of too many pain pills and prescribing them too often?
MR. LIMBACHER: Object to form.
BY MS. SCULLION:

Q. Is that something that Endo agreed with as a principle underlying its anti-diversion policies?
MR. LIMBACHER: Object to form.
THE WITNESS: I would say very much it was an underlying principle with the activities undertaken, yes.
BY MS. SCULLION:
Q. So does Endo agree then that a cause of the opioid epidemic was prescribing of too many pain pills and prescribing them too often?
MR. LIMBACHER: Object to form and object on the grounds that it falls outside the scope of the topics on which he has been designated.
THE WITNESS: I think Endo has acknowledged, even in some of the documents we saw today, that the opioid epidemic is large and requires the attention and activity of many different constituencies, which would include all of the things we've talked about here.
BY MS. SCULLION:

Q. Including the phenomenon of prescribing too many pain pills and prescribing them too often?
MR. LIMBACHER: Object to form, same objections.
THE WITNESS: And specifically to that, I would point to the training and the adherence to FDA labeling that underpins promotion. To the extent that Endo could control whether physicians understood clearly the appropriate use of its medicines, beyond that, as you well know, physicians are free to prescribe what they would like to and to whom, but to the extent that Endo could control that in terms of promotion and other activities, yes, that underpinned the RiskMAP, the REMS, the ADD and the company activities.
BY MS. SCULLION:
Q. And did another principle that Endo took into account in designing its anti-diversion policies, was another principle that prescription opioids were often the gateway

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to heroin addiction?
MR. LIMBACHER: Object to the form and object as falling outside the scope of the topics on which he's been designated.
THE WITNESS: I don't know.
MR. LIMBACHER: We've been going about an hour. Is this a good spot for a break?
BY MS. SCULLION:
Q. Do you know who Ms. Rendon is?
A. Not other than what I read here on the paper.
Q. At the time she was the U.S. Attorney for the Northern District of Ohio, correct?
A. That's what this says, yes.
Q. Are you aware that she is today Endo's counsel in this case?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm not aware of that, no.
MS. SCULLION: We can take a break.

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THE VIDEOGRAPHER: Off the record, 2:23.
(Brief recess.)
THE VIDEOGRAPHER: The time is now 2:39 p.m. We are back on the record.
MR. LIMBACHER: Jen, I just wanted to put on the record, you and I talked briefly during the break with regard to how late we might go today and what we anticipate for tomorrow.
My understanding is that you do not think you're going to be able to finish your questioning today. The witness is available to come back tomorrow. He can be here, he believes, and ready to go starting at 2:30. My preference, as I indicated during the break, is that we go tonight until a reasonable hour, approximately 7:00 to try to get as much done today so that tomorrow can be relatively brief, and we can complete the deposition as quickly as possible.

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My understanding is, for reasons I don't fully understand, you want to shut it down today at 5:30, and I would strongly encourage you to agree to let's go beyond 5:30, let's go until 7:00. I think that's a reasonable time for everybody, and that will make it much more likely that we're going to be able to complete the deposition tomorrow by a reasonable hour.
MS. SCULLION: And as we also discussed off the record and in some prior e-mails, first we do appreciate the witness' ability to come back tomorrow beginning at 2:30. We had noticed the deposition to go day to day, and we had specifically given a heads-up a few weeks ago that we did expect your deposition to go for two days, given the breadth of the topics on which you're designated, as well as our intent to ask you questions in your personal capacity.
And with that, although in cases where we only expected to have a

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deposition for one day, we've been willing to go what I would call these marathon depositions until late in the evening. There's really just -- there's no need. We did give the heads-up. We give it for a reason. We planned for the two days.
I was only given notice, I apologize, last night or yesterday, I should say, probably yesterday afternoon that you would not be available tomorrow morning but only in the afternoon.
Nonetheless, we had planned for two days, and you can correct me if I'm wrong, but my understanding is that when there have been depositions going for two days planned in this case, that the practice has been to stop at around 5:30 or 6:00 and then continue the next day. That's our intent. We intend to use, you know, our full-time, we're trying to be efficient about it.
I will say that our disagreements as to the scope, in particular, have

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caused us to have to rejigger our approach to the examination, so that's also problematic for us, but we will go till 6:00 today, and then we can reconvene tomorrow.

The witness did indicate, and I very much appreciate it, that he is able to then sit for as long as it takes, I think you said, tomorrow. We don't intend to go till 10:00 or 11:00 at night. And so if we get to a point tomorrow where we still have questions that we need to take -- examine you on and have not used our time and it's getting too late, we will just reconvene for another day.

MR. LIMBACHER: Well, if you think you're going to need two full days with this witness, all the more reason, if we're going to resume tomorrow at 2:30, that we should go later than 5:30 today. I'm not sure I understand what the thinking is as to why you're so unwilling to make full use of the time

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today. If we shut it down at 5:30, I'm not even sure we're going to have had a total of seven hours of questioning today.

So, again, I would ask that we go past 5:30, we go past 6:00, we get as much done today as we can so that realistically we can get it finished tomorrow because I'm not interested and I don't think we're obligated to bring him back for a third day.

MS. SCULLION: So I don't think we need to spend more time on this. We do think that we are entitled to the two full days. Again, we hadn't known he wasn't going to be available in the morning. We had given a heads-up that we wanted him for two full days. We can discuss this if and when it becomes an issue.

MR. LIMBACHER: I'll just note from my experience that Kristin Vitanza was a 30(b)(6) witness as well, and we finished her up as both a fact witness

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and a 30(b)(6) witness in one day.

MS. SCULLION: And that hasn't happened always. For example, I think Dr. Shusterman, you know, was two days, also 30(b)(6) and a fact witness, and I think -- again, I think the first day was ended at 5:30 or 6:00 or so.

MR. LIMBACHER: Just would point out that Mr. Lortie doesn't work for the company anymore and to try to have this deposition extend into a third day is really unreasonable. Under the circumstances, we should go well beyond 5:30 today to try to get this finished tomorrow.

MS. SCULLION: And, again, we're not trying to be unreasonable. We hadn't known that you weren't available tomorrow morning until we were told that yesterday. We had asked for you for two days. So, again, let's deal with it if the issue is still live at the end of tomorrow.

(Document marked for

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identification as Endo-Lortie Deposition Exhibit No. 17.)

BY MS. SCULLION:

Q. Let me hand you what's been marked as Exhibit Number 17. And Exhibit 17 is Bates stamped ENDO-OPIOID_MDL-01056072, and we've stamped it in the upper right-hand corner E1010.

And, Mr. Lortie, asking you in your capacity -- these questions would be in your capacity as a corporate representative on the role of wholesalers and distributors and retailers in combating abuse and diversion of opioid products.

So if you'll look at Exhibit 17, it's a series of e-mails attaching a McKesson distribution agreement and various amendments thereto. I'm not going to be asking you to go through the entirety of these contracts. And if I can direct your attention, though, to page in the upper right-hand corner E1010.10?

A. 1010.10.

Q. You got it.

And you'll see "Article 2 Mutual

Obligations," and under Section "2.3 Core Services," there's a discussion of the various services that McKesson will perform and provide to Endo Pharmaceuticals, and the third service listed there says 852 data.

Do you have -- are you familiar with 852 data in the context of a distribution agreement?

A. I recognize the term. I'd have to think about refreshing my recollection. It's been a while, so I recognize that it's a term used in this context, but I don't recall specifically what it's referring to.

Q. Okay. Let's go down to vi under 2.3 refers to "Chargeback Processing."

Do you see that?

A. Yes, I see that. I see that vi.

Q. Are you familiar with the concept of chargebacks in the context of distribution agreements between Endo and wholesalers?

A. Generally, yes.

Q. And in this paragraph 6 it states, "Accurate and timely processing and reconciliation of Customer chargebacks due to

contract pricing between the Customer and Manufacturer."

Did I read that correctly?

A. That's what's written here, yes.

Q. Okay. And if you go to page -- sorry -- E1010.8, you see under "Article 1 Definitions" at the very bottom is the beginning of -- is the definition of "Customer"?

A. Yes, I do see that.

Q. Okay. And it says that the "Customer means the purchaser of products from McKesson, including but not limited to national and regional retail chains, institutional providers, and retail independent pharmacies."

Did I read that correctly?

A. Yes, you did.

Q. Is that consistent with your understanding of who some of the purchasers of products from McKesson would be, those categories?

MR. LIMBACHER: Object to form.

THE WITNESS: I have no reason to question that that's how McKesson defines customer across their, you know,

various manufacturers that they have distribution agreements with.

BY MS. SCULLION:

Q. Okay. And I just showed you that for your reference. If you'll now go back to page we were on E1010.10, which discusses the chargeback processing in 2.3 vi. The reference here to customer chargebacks due to contract pricing between the customer and manufacturer, the manufacturer here is Endo, correct?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. It's an Endo-McKesson contract, right?

A. I believe it is, yeah, it looks to be.

Q. Okay. Do you know what is referred to -- what is referenced by contract pricing between the customer and Endo? Did Endo have contract pricing with any of the entities that we saw fell within the definition of customer, that is national and regional retail chains, institutional providers and retail independent pharmacies?

MR. LIMBACHER: For all of the products that are identified here, or are you limiting this?

BY MS. SCULLION:

Q. We can just -- we can limit that to Opana ER.

A. My recollection is that national and regional retail chains, yes, we had relationships with. Institutional providers, I don't recall specifically. It may or may not have been, and that would be a hospital or a hospital system, and my recollection is that retail independent pharmacies, we did not do direct shipping to. Whether or not McKesson -- how they had a view to that was something I don't recall specifically, but, yes, national and regional retail chains for sure.

Q. And by national and regional retail chains, those would be pharmacy chains, correct?

MR. LIMBACHER: Object to form, and I object to the extent it falls outside the scope of the topics on which he's been designated.

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MS. SCULLION: I'll connect it up.
THE WITNESS: I would say that that's the CVSs and the Rite Aids of the world and the like.
BY MS. SCULLION:
Q. Okay. And the chargebacks that are referenced here, those would be indications of how much the customer actually paid to McKesson versus the -- strike that.
That would be a reference to the amount that the customer, such as Rite Aid, would have paid under the contract pricing as compared with the amount that McKesson paid to Endo for the product, correct? That's the difference is that chargeback?
MR. LIMBACHER: Object to form and foundation. Objection to the extent it falls outside the scope of the topics on which he's been designated.
THE WITNESS: Yeah, it's been a while since I've thought about the intricacies of the contract processing. We certainly had expert professional

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people who did this every day, but I think, generally, the way you describe it is, to my recollection, accurate.
BY MS. SCULLION:
Q. Okay. And are you familiar with the concept that the chargeback data then would show the individual purchases that were made under the contract pricing by the national and regional retail chains?
MR. LIMBACHER: Same objections.
THE WITNESS: My recollection is that that would happen but at that level of a national or regional chain and not deeper than that.
BY MS. SCULLION:
Q. Okay. And you mentioned Ms. Walker, Lisa Walker and her function before.
Did her group also oversee processing and administration of the chargeback -- chargeback process?
MR. LIMBACHER: Same objections, well outside the scope of the topics on which he has been designated.
THE WITNESS: No, that's not my

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recollection of Lisa's role.
BY MS. SCULLION:
Q. Who -- was there a group within Endo that was charged with administering the chargeback process?
MR. LIMBACHER: Same objections.
THE WITNESS: There was, yes.
BY MS. SCULLION:
Q. Okay. Do you recall the name of that group?
A. We called that, as I recall, a contract and pricing operations or something like that.
Q. Okay. And so that group would have seen again the data showing the purchases by national and regional retail chains from McKesson, right?
MR. LIMBACHER: Same objections, outside the scope of the topics on which he's been designated.
THE WITNESS: At some macro level, yes, I believe that's true.
BY MS. SCULLION:
Q. Okay. So in that respect, Endo

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had access to information about purchases by its customer's customers, that is McKesson being Endo's customer and then McKesson's customers?
MR. LIMBACHER: Same objections.
THE WITNESS: And same answer, at some high level, at some macro level, not at an individual pharmacy level, for example, but at a national or regional level.
BY MS. SCULLION:
Q. And did Endo have any policies or procedures for trying to make use of that chargeback data as part of its monitoring for diversion or abuse of Opana ER?
A. I don't think that information would have added any value really, because it was at such a macro rolled up level that it wouldn't have been -- unless I'm missing something, a set of data that would have really been able to show anything. So I'm not aware that that was used, no.
Q. Okay. So the answer is, no, you're not aware of any such policy or procedure, correct?

MR. LIMBACHER: Object to form.
THE WITNESS: Correct, because I'm not sure that it would have been valuable, so we wouldn't have put that in place.
BY MS. SCULLION:
Q. Did Endo have any policy or procedure by which it sought to ask the wholesalers to assist it in its anti-diversion and abuse efforts with respect to Opana ER?
MR. LIMBACHER: Object to form.
THE WITNESS: My recollection is that Endo recognized, as did the wholesalers and distributors, that each played an important role and each had its own set of regulations to adhere to and also to ensure that we were comfortable that our distribution or wholesale partners were doing their job according to regulations and law, those languages were in the distribution services agreements, in other words, to ensure to Endo that McKesson in this case was adhering to all applicable

rules, regulations and laws pertaining to all aspects of their distribution.
BY MS. SCULLION:
Q. But, for example, did Endo, as part of its anti-diversion efforts, ask its wholesaler, distributor such as McKesson, to provide Endo with information about the downstream distribution of Endo's products so that Endo could, for example, monitor for suspected diversion or abuse?
MR. LIMBACHER: Object to form.
THE WITNESS: What I would say is Endo depended on the wholesaler distributor to operate according to the rules and regulations that pertained to them and thereby entrusted that to them. So to the extent to which Endo checked beyond that, I don't recall.
BY MS. SCULLION:
Q. Okay. Do you recall whether at any point in time -- strike that.
I'd like to ask you some questions with respect to Endo's policies and procedures for enforcing laws and regulations

concerning promotional materials.
A. Okay.
Q. That's one of the areas in which you have been designated, correct?
A. Yes.
Q. Okay.
MS. SCULLION: Could we have exhibits 1458 and 1456.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 18.)
BY MS. SCULLION:
Q. I'll hand you what's been marked as Exhibit Number 18. I'm going to need a copy.
And Exhibit 18 is Bates stamped END00747325, and we have marked it in the upper right-hand corner E1458.
Mr. Lortie, do you recognize Exhibit 18 as Endo's Corporate Policy for the Promotional Materials Review Board, and if you go to the last page of the exhibit, it says it was revised as of 1/12/2007?
A. Yes, I see that.
Q. And do you recognize this as that

corporate policy?
A. Yes, as of that time I recognize and I've reviewed this.
Q. Okay. You did review this in --
A. I did.
Q. -- the course of preparing for today's deposition? Okay.
MS. SCULLION: And then can we have 1456.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 19.)
BY MS. SCULLION:
Q. Now I'm going to hand you what's been marked as Exhibit 19.
And Exhibit 19 is Bates stamped END00747404, and we've marked it in the upper right-hand corner E1456. And this is the standard operating procedure dated May 2013 for the Marketing and Advertising Review Committee, and it says (MARC).
Did you review this document also in preparation for today's deposition?
A. Yes, I think I did.

Q. Okay. And we discussed a little bit earlier the Promotional Materials Review Board, PMRB, and MARC.

Can you tell me, to the best of your understanding, was there any difference in the operation of PMRB versus MARC?

A. My understanding and my recollection as to the differences between PMRB and MARC is that as the company evolved and became a company not just focused on branded products and a small generic business in 2007, but by 2013 a branded, a generic, a medical device, a healthcare information technology business, there was a requirement to make sure that we had the appropriate operating procedures in place to cover to the extent that they pertained in some way to any of those businesses so the MARC approach evolved to take that into consideration.

I believe, also, that there was a technology change, such that there was a system put in place, the Zinc system that enabled sort of realtime review and computer review as opposed to pencil and paper review or a lack of

more sophisticated description, so I think those are two of the major changes.

What didn't change is that their policies that required review and sign-off across a multi-disciplinary team on any promotion that was used with any sort of healthcare customer, and that team comprised of not just marketing but also legal, regulatory, experts and others, but that's -- you know, essentially this is the sign-off procedure to ensure that any promotional material or claims adhered to the FDA requirements were well supported by medical literature and things like that.

Q. Okay. So if I understand correctly, under PMRB, the process was sort of pen to paper, as you said, not electronically done, review process for promotional materials, correct?

A. That's my understanding. It may have been that there was some ways to move the things around by e-mail, but I know that MARC and Zinc became much more sophisticated, dedicated system to allow reviewers to do that

work I think in an aim to be most efficient.

Q. Okay. And just sticking on Exhibit Number 19, the MARC SOP. I lost my marked copy of MARC.

Do you understand that the Zinc system included an audit trail to allow you to audit the process?

A. I believe that was true. I don't -- I don't recall specifically. I wasn't on the MARC team nor the PMRB. I was on the escalation occasionally, but the nuts and bolts of how the system worked is something that I'm not all that familiar with.

Q. Did you make any attempt to become familiar with that in preparation for today's deposition?

MR. LIMBACHER: Object to form.

THE WITNESS: At that level of detail specifically to the audit trail, no, I did not.

BY MS. SCULLION:

Q. Okay. I believe, and we'll try to find that, I think there's a reference to there being an audit trail in Zinc.

When review of promotional materials was performed under the PMRB, what kind of auditable records existed of that review?

A. I don't specifically know. I would assume that there was paper kept. I'm sure that there was a file in the regulatory department because it would have been their job to report these things and do the necessary submissions as required by the FDA, but, specifically, I don't know what the audit process were, what was required.

Q. Now, as you said, those are all assumptions you're making, you don't know that sitting here today, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I don't know that, correct, but I would be -- you know, this falls into sort of standard -- I know what the regulatory people do, they keep records of things. It's their job to fulfill the very clearly delineated correspondence with the FDA. So in that context, I'm quite sure that they would

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have kept copies of everything that came through PMRB or at least those things that were approved.
BY MS. SCULLION:
Q. Do you recall that in connection with the Lidoderm investigation and the anticipation of the corporate integrity agreement, there was a review of Endo's compliance procedures?
MR. LIMBACHER: Are you asking these questions in his capacity as a 30(b)(6) witness?
MS. SCULLION: I am, because one of the aspects of the 30(b)(6) is with respect to compliance as it applied to enforcement of abuse and diversion laws and regulations.
THE WITNESS: I don't recall specifically --
MR. LIMBACHER: Excuse me.
THE WITNESS: Sorry.
MR. LIMBACHER: I would object to the extent it falls outside the scope of the topics on which he's been

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designated.
You can answer.
THE WITNESS: I don't recall specifically with regards to that Lidoderm question.
BY MS. SCULLION:
Q. Okay. Just one second. We'll come back to that when we find it. You guys keep will looking.
Under both the PMRB and the MARC process, am I correct that the -- I think, as you were explaining, that the process itself was really run by regulatory, legal and medical with, as we understand it from Ms. Vitanza's testimony, the marketing folks serving as presenters, initiators I think is the word, initiators of review on particular pieces.
Is that your understanding?
A. That is, yes.
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. And so in no way should marketing really be running the PMRB or MARC process, correct?

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MR. LIMBACHER: Object to form.
THE WITNESS: I think it depends on who you mean by "marketing." Certainly at a certain point as MARC came to be, I do recall that there was a responsible party that reported up through the commercial operations and whose job it was to be project manager of the process, not an initiator, not an inputter, not a creative -- not a reviewer but -- and that person reported up through commercial operations. So if that's how you're defining marketing, then my answer would be different. But marketing as defined by product manager or anybody involved in -- directly in commercialization, they were an initiator of the material to be reviewed.
BY MS. SCULLION:
Q. Okay. And do you recall that -- strike that.
Was it Endo's policy to have product specific guides as the foundation for

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the promotional materials review process?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm not sure what that means.
BY MS. SCULLION:
Q. Did -- was a dossier prepared for each product that gave some of the basic information about the product, the label, labeling history and concepts that had been agreed on to serve as the basis for appropriate promotion for a product?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't recall specifically. Those themes I would be sure that were part of every consideration, but I don't recall a specific dossier or product guide, as you said. It could be, but I wasn't -- I wasn't involved in the day-to-day operations of either of these two committees or processes, that Kristin, for example, would have been much more close to the process.
BY MS. SCULLION:

Q. So, for example, then you also would not be able to testify today whether the product specific guide for Opana ER in its original, not reformulated but original formulation was ever completed?

MR. LIMBACHER: Object to form, object to the extent it falls outside the scope of topics on which he's been designated. He's here to testify with regard to the general process and not with regard to the details that you're asking him about now.

THE WITNESS: I don't know, because I'm not aware of such a guide.

BY MS. SCULLION:

Q. Okay. Just going back, again, to the general process for promotional materials review. I think, as we've discussed, it would be initiated by someone from marketing, correct?

A. Typically, yes.

Q. Okay. And then, typically, there would be a reasonable time frame in which the members of the review board or MARC would have to then review the promotional materials,

correct?

A. That's my understanding.

Q. Okay. And only after that review had happened if there were disagreement as to how to proceed would there be potential for an escalation above the board, correct?

A. That's my understanding, yes.

Q. Okay.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 20.)

BY MS. SCULLION:

Q. Let me hand you what has been marked as Exhibit 20, and this is going back to the questions concerning review of Endo's compliance procedures in connection with the expected CIA, and Exhibit 20 -- do you have Bates numbers? Thank you. It bears Bates number EPI002412332.

And, Mr. Lortie, if you look at the first page of the PowerPoint, it states it's a compliance overview and says in the lower left-hand corner "ELC, March 21, 2013."

Was ELC the abbreviation for

Executive Leadership Committee?

MR. LIMBACHER: Just note my objection. If you're asking these questions in his role as a 30(b)(6) witness, I believe it goes beyond the scope of the topics on which he's been designated.

BY MS. SCULLION:

Q. Just so you know the reason we disagree with that is, again, one of the topics on which you've been designated are -- is with respect to changes in policies and procedures and reasons therefor, and we believe this document goes directly to questions of changes in policies and procedures that, among other things, impacted efforts to ensure compliance with applicable laws and regulations for the sale, marketing, distribution, et cetera, of opioids.

I'm sorry. I was asking on the lower left-hand corner of the first page of the PowerPoint where it says ELC, is that Executive Leadership Committee?

A. It was at that point in time,

yes.

Q. Looking at Exhibit 20, do you recall seeing a compliance overview in March of 2013?

A. I was not a member of ELC at that point, so no.

Q. Were you aware that -- looking at this, does this refresh your recollection that compliance overview was undertaken around that time?

A. I don't recall.

Q. Okay. If you'll look at the second page of the PowerPoint, it says on the first bullet point "Compliance function established in 2004 with increased focus as a result of Lidoderm investigation (January 2007)."

Before 2004 did Endo have any compliance function?

MR. LIMBACHER: Again, note my objection to these questions to the extent that it's beyond the scope of the topics on which he's been designated.

THE WITNESS: I'm not sure. That

predates me by several years. I'm aware of the compliance function that was in place when I was there.

BY MS. SCULLION:

Q. Okay. If you will go to page 6 of the PowerPoint, and the third major -- second major bullet point down refers to "Recent precedent setting requirements," and under that is a bullet point "Eliminate territory/individual sales goals for sales personnel and direct managers."

Did Endo ever consider changing its policies with respect to territory and individual sales goals for sales personnel and direct managers in connection with the promotion of Opana ER?

MR. LIMBACHER: Object as beyond the scope of the 30(b)(6) topics on which he's been designated.

THE WITNESS: And, sorry, can you just ask the question it again so I can answer correctly.

BY MS. SCULLION:

Q. Sure. Did Endo ever consider

changing its policies with respect to territory and individual sales goals for sales personnel and direct managers in connection with the promotion of Opana ER?

MR. LIMBACHER: Same objection.

THE WITNESS: Well, changing the policy is different from eliminating, that's why I asked for clarification. So if you're asking did we consider eliminating as it's outlined in this bullet point, that's one question. Changes to individual sales goals happened as a matter of course.

BY MS. SCULLION:

Q. Thanks for the clarification.

Did Endo ever consider eliminating the territory individual sales goals?

MR. LIMBACHER: Same objection.

THE WITNESS: Not that I'm aware of.

BY MS. SCULLION:

Q. If you go to page 9 of the PowerPoint, the first bullet point says, "CIA

would necessitate a significant increase in monitoring for Endo Pharmaceuticals" and then goes on to explain "Endo's monitoring programs has not included records reviews or non-promotional activities" -- I think it should be of non-promotional activities -- "and current resourcing would be insufficient to meet CIA requirements."

Did Endo have any records review as part of its policies and procedures to ensure compliance with the laws and regulations for the sale, marketing and distribution of Opana ER?

MR. LIMBACHER: Object as beyond the scope of the topics on which he's been designated.

THE WITNESS: So, you know, I'm trying to clarify, because as you pointed out the word or here may be incorrect. It could be of, it could be on, and it does slightly change the question.

I don't recall specifically how we defined or how the author here would have defined records reviews.

What I can say is that the entirety of the period that I was at Endo and, again, going back to the 2007 RiskMAP, there's a comprehensive program that involved many different elements, all intended specifically for Opana ER to do our part in mitigating abuse and diversion and other things.

To the extent that -- you know, and, again, I'm happy to look at something to remind me what records reviews were and how it's defined here, but beyond that, I'm certainly not going to say that there was nothing in place, but I don't know what the author is speaking about in this particular slide.

BY MS. SCULLION:

Q. Do you have an understanding of the concept of record review in connection with compliance?

A. This is what I'm asking for clarification on because I need some help in recalling what the definition of that specifically is in this context. So if you've

got something, I'd be happy to look at it.
Q. Next bullet point says that "In 2012, 17 speaker program reviews and 8 field ride-alongs were conducted due to resource constraints, travel limits and sales force restructuring."
Is that accurate, that in 2012 only 17 speaker program reviews were conducted due to resource constraints, travel limits and sales force restructuring?
MR. LIMBACHER: Object to the form and object to the extent it falls outside the scope of the topics on which he's been designated.
THE WITNESS: I don't know.
BY MS. SCULLION:
Q. Did Endo cut back in 2012 on field ride-alongs that would be used to ensure compliance with laws and regulations concerning the promotion of Opana ER?
MR. LIMBACHER: Same objections.
THE WITNESS: I don't know. I don't recall.
BY MS. SCULLION:

Q. Do you know what efforts Endo -- strike that.
Do you know what policies Endo had in place for the audit of the PMRB review of marketing materials?
A. I think we've answered that question before. I don't recall specifically the details of the elements of such an audit.
Q. I mean, do you know one way or the other whether -- do you know one way or the other whether the process was ever audited?
MR. LIMBACHER: Object to form and, again, outside the scope of the topics on which he's been designated.
THE WITNESS: To the extent that the FDA or other regulatory bodies required such an audit or such recordkeeping, I'm sure that Endo followed those policies and procedures. I'm just not aware of what those were.
BY MS. SCULLION:
Q. Okay. So going back to the policies and procedures with respect to ensuring the accuracy and legality of promotional

materials, do you understand that for promotional materials, the label defines the product?
MR. LIMBACHER: Object to form.
THE WITNESS: The label defines the product, what I understand is that all promotion has to be supported in an alignment with the claims and indications and information and the prescribing information.
Is that what you mean?
BY MS. SCULLION:
Q. Yes. It means that the promotional materials can't go beyond what's in the label, correct?
A. That's correct.
Q. Can't contradict what's in the label, right?
A. That's, I think, a fair statement, yes.
Q. And the promotional materials can't contradict the label either expressly, right?
A. As you recently asked, yes, I

believe that's true.
Q. And can't do it by implication either, right?
MR. LIMBACHER: Object to form.
THE WITNESS: I mean, I'm not sure what you mean by that.
What I will say is all promotion has to be in alignment with the label, has to be supported by medical evidence, has to be signed off by medical, regulatory and legal professionals and also has to be submitted to the FDA, at least at time of use, to give them a chance to weigh in if they have any objections.
BY MS. SCULLION:
Q. Well, let me ask you specifically with respect to Schedule II opioids like Opana ER.
You'd agree that Endo couldn't design promotional materials that were intended to send a message to healthcare providers that Endo's products were less risky than other Schedule II opioids?

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MR. LIMBACHER: Object to form.
THE WITNESS: By design or by put into use? I mean, I'm drawing that distinction because it's an important one.
BY MS. SCULLION:
Q. Design.
A. So is your question at any point would Endo or any of its agencies have mocked something up for consideration that ultimately may be decided was in conflict with the label, or were such -- was promotion allowed to come through the system and out into use that qualified?
Q. Right. Could Endo have put into use a promotional piece that was intentionally designed to send healthcare providers a message that Endo's opioid product, Opana ER, was less risky than other long-acting opioids?
MR. LIMBACHER: Object to form and object as outside the scope of the topics on which he has been designated. You're now asking him questions with regard to topic number 11, which he has

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not been designated on.
MS. SCULLION: I'm asking with respect to topic number 13. I understand --
MR. LIMBACHER: Respectfully, I disagree.
MS. SCULLION: I understand you made an objection.
THE WITNESS: Whatever promotion was put into use should adhere completely to the regulations and should be in -- supported by medical literature and in alignment with the product labeling.
BY MS. SCULLION:
Q. The question is would you agree that it'd be improper to put into use a piece of promotional material that was intentionally designed to send the message that Endo's Opana ER was less risky than other long-acting opioids?
MR. LIMBACHER: Same objections.
THE WITNESS: I think it depends on what other long-acting opioid. I

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mean, I would need to see the specifics to be able to answer that accurately because there may be some specific instance that I'm not thinking of. So, again, my answer until I see something in detail is that all promotion that was put into use by the company and passed through either the PMRB or the MARC process and been signed off by medical, legal and regulatory experts and had been submitted to the FDA. Beyond that, it's hard for me to answer that question unless I see specifically what you're speaking of.
BY MS. SCULLION:
Q. So you think it would depend on the particular promotional material?
MR. LIMBACHER: Object to form.
THE WITNESS: I'd like to see what you're referring to so I can give you an accurate answer.
BY MS. SCULLION:
Q. I'm asking in terms of the policies and procedures that were used by Endo

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in reviewing promotional materials for the promotion of Opana ER. Was that one of the principles that informed that process?
MR. LIMBACHER: Object to form.
THE WITNESS: The principles were any piece put into promotion for use by our company was vetted through either the PMRB or the MARC process by medical, legal, regulatory professionals to ensure its compliance with regulations, its portability by the medical literature and its alignment with the product label.
BY MS. SCULLION:
Q. So, for example, if Endo had market research that told it, well, doctors hearing these particular words understand those words to convey that the product is less risky and put them at ease about using the product, it would be okay for Endo to use those words in a piece of promotional literature with respect to Opana ER in the field; that would be okay?
MR. LIMBACHER: Object to form and object as beyond the scope of the

topics on which he's been designated.
THE WITNESS: Again, it would be very helpful to see the specific piece of promotion that you're referring to and the specific type of market research because on -- blanket statements are not helpful for me to be able to answer that accurately.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 21.)
BY MS. SCULLION:
Q. Okay. Let me show you what's been marked as Exhibit Number 2.
And Exhibit Number 21 is marked -- is Bates stamped END00401724, and we've marked it E1604.1 in the upper right-hand corner.
Mr. Lortie, this is the Endo Pharmaceuticals "Health Care Compliance Guide" effective -- well, yeah, it says effective as of June 1, 2005, revised in May 2009 in the lower left-hand corner.
Do you see that?

A. Yes, I see that.
Q. Okay. Are you familiar with the healthcare compliance guide?
A. I have not seen this, no, so I'll take a few minutes if that's okay.
Q. You can do that off the record. I actually only have a question for you about one page of the Health Care Compliance Guide. I take it you did not review this in connection with your preparation for today's deposition?
A. I don't recall reviewing it. If you'd like to point me to the page, but I'd still --
Q. Sure.
A. -- reserve the ability to understand the context.
Q. The page is E1604.18?
MR. LIMBACHER: I'm sorry. Which page?
MS. SCULLION: 1604.18.
BY MS. SCULLION:
Q. Are you with me?
A. Yeah, I'm just understanding the chapter, and I now recognize I have seen this in

my preparation.
Q. Terrific. And on page E1604.18, you see the chart under the heading "Advertising and Promotion - Examples of Permitted vs. Prohibited Activities."
And do you see on the right-hand side it says, among other prohibited activities is a third one down, "Statements about safety that minimize or are inconsistent with the information in the package insert."
Do you see that?
A. I do, yes.
Q. And so that was prohibited with respect to promotional materials for Opana ER or any other product, correct?
A. As I think I've testified, the expectation would be that any statements are consistent with the information in the package insert.
Q. Right. But this goes just beyond whether they're consistent or inconsistent.
It also says you can't minimize the statements about safety, correct?
MR. LIMBACHER: Object to form.

THE WITNESS: Yeah, I see that written here.
My knowledge of the program is that it's consistency with the label that's critical and to the extent that that would be true or not true, again, we'd have to see what exactly the claim is in question.
BY MS. SCULLION:
Q. Well, I'm sorry. As Endo's corporate representative with respect to the policies used to ensure compliance with the laws and regulations for promotion of Opana ER, are you telling me that it was not Endo's policy, as reflected in its Health Care Compliance Guide that it was prohibited to use statements about safety that minimized the information in the package insert?
MR. LIMBACHER: Object to form, and I think you've misstated the topics on which he's been designated as a 30(b)(6) witness.
THE WITNESS: Again, my understanding and my experience has been

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that anything that goes out in promotion passes through the PMRB or the MARC process, is signed off by the appropriate professionals that satisfy that the statements about safety are consistent with the information in the package insert and/or supported by PMRB approved promotional pieces it says here and that it's consistent with the label.

BY MS. SCULLION:

Q. Is there a distinction in your mind between whether a statement is consistent with the package insert and whether even if consistent it might minimize the information in the package insert?

MR. LIMBACHER: Same objections.

THE WITNESS: I mean, I don't know what minimize means. That's not a very precise statement, so I will say that, you know, I see it written here and I understand that, but for me it's consistency with the label and sign-off in each case by the appropriate medical, legal and professional representative

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that determined whether or not something would be acceptable for use.

BY MS. SCULLION:

Q. So, to your understanding, the only line is whether it's consistent or inconsistent with the package information, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: In general --

BY MS. SCULLION:

Q. Package insert.

A. -- that is my understanding as to the, you know, core guiding principles. Again, all promotion at the time of use was submitted to the FDA as an additional step for them in case our team got it wrong, and the FDA had an opportunity to review all materials, and there are various mechanisms that FDA can use to respond to sponsors in terms of whether or not they find material to be acceptable.

Q. And you agree, though, that as part of your team trying to get it right, according to the Health Care Compliance Guide, they were prohibited from approving statements

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about safety that minimize the information in the package information insert, right? That was the policy of Endo, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: That was according to the Health Care Compliance Guide on that date, yes.

BY MS. SCULLION:

Q. You'd also agree that if FDA had specifically told Endo that it couldn't say X about a product, that Endo should not then say X about a product in its promotional materials?

MR. LIMBACHER: Object to form.

THE WITNESS: I think that's a fair statement, I would agree.

BY MS. SCULLION:

Q. And same thing with respect to the detailing by sales reps in the field, if FDA had said you can't say X, the sales reps shouldn't be saying X about the product in the field, right?

A. I think it's the same question, yes. If the FDA explicitly prohibits a given bit of language, companies should not be doing

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that.

Q. Now, is it just that FDA prohibits a specific -- specific words or was Endo also required to prohibit similar words that conveyed the same message as the words that the FDA had prohibited?

MR. LIMBACHER: Object to form to the extent it falls outside the scope of the topics on which he's been designated.

THE WITNESS: That's a difficult one that requires examination of a specific piece of material or a specific piece of language because, as you know, specific words are prohibited. Conceptually, there's a lot of variability in what one party might consider acceptable, and, ultimately, it's we trust the process to make sure we get that right.

BY MS. SCULLION:

Q. Well, do you think it'd be appropriate if -- for Endo having seen that the FDA struck specific language to try to go back

and craft language that conveys the same message but doesn't just use the same words that FDA struck; would they be appropriate undertaking?

MR. LIMBACHER: Object to form.

THE WITNESS: I don't know how to answer that question because that's a -- that's a specific circumstance.

BY MS. SCULLION:

Q. Wouldn't that be an effort to just end run FDA's decision to strike certain language?

MR. LIMBACHER: Object to form.

THE WITNESS: No, I can't agree to that statement that you just made, no.

MS. SCULLION: I was going to start a new topic. I'm not aware of how long we've been going so if we -- it's a good time for a break.

MR. LIMBACHER: It's almost an hour, so maybe we'll take a short break.

MS. SCULLION: Yeah, that's fine.

MR. LIMBACHER: Thank you.

THE VIDEOGRAPHER: The time is

3:35. We are now going off the record.

(Brief recess.)

THE VIDEOGRAPHER: The time is 3:48. We are now back on record.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 22.)

BY MS. SCULLION:

Q. Mr. Lortie, let me hand you what's been marked as Exhibit Number 22.

And Exhibit Number 22 is a copy of the -- of material that your counsel provided to us in advance of your deposition, and it is, to my understanding, a chart showing the claims that we've asked you to speak to in response to topic 13 of the 30(b)(6) notice on the left-hand side, and on the right-hand side are the supporting references for those claims.

Mr. Lortie, did you review Exhibit 22 before today's deposition?

A. Yes, I did.

Q. Do you know who prepared Exhibit 22?

A. This was prepared by our counsel

in preparation for this topic.

Q. Did you assist in its preparation?

A. I did not prepare it. I reviewed it and ensured by checking and referring to some of the references so that I could familiarize myself with the material.

Q. Okay. The material listed as supporting references on the right side of Exhibit 22, were those materials that were cited contemporaneously as support for the claims, meaning at the time that the marketing piece listed in the left-hand column of the chart was authorized for use?

MR. LIMBACHER: Object to form, outside the scope of the topics on which he's been designated.

THE WITNESS: I believe that to be the case, but I'm not sure I personally checked the dates on each one, but that's my understanding.

BY MS. SCULLION:

Q. Do you have an understanding about whether -- what information exists in

Endo's records that would allow one to know whether these materials were, in fact, the materials cited contemporaneously to support a claim in a given piece of marketing -- sorry, promotional material?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not sure I understand what you're asking.

BY MS. SCULLION:

Q. If I want to go find out whether, in fact, a particular study, for example, had been cited at the time that a particular promotional piece was approved, are there records that allow me to determine that?

MR. LIMBACHER: Object to form.

THE WITNESS: I suspect that there are. My recollection is I -- you know, just in general with any piece is the references are often, if not always, included on the piece itself. So it almost stands as its own record, but I'm quite sure that Endo did maintain the references and how long they maintained them for and what the audit requirements

are, I'm just not familiar with the specific details.

BY MS. SCULLION:

Q. I mean, you raise a good point. There are certain promotional pieces that we've seen that do, in fact, have footnotes and citations to references.

Is that what you were just referring to?

A. That's correct.

Q. But that's not always the case with respect to promotional materials that Endo used in connection with opioids, right?

A. I'm not sure. My recollection is that that is the standard that is the customary not just for Endo but for all promotional material I can recall across my career, whether there are exceptions to that for some reason, I'm not sure, but, in general, the pieces always, to my recollection, would cite the supporting references right on the piece itself.

Q. Okay. If you look in the left-hand column of Exhibit 22 under the column for "Plaintiffs' Claims," if you will go to the

second page of Exhibit 22, that column. You see where it says note, claim numbers 3, 4 and 5 not included in final approved materials?

A. I see that referenced here, yes.

Q. Are there records within Endo that would allow one to determine whether any given document was a final approved piece of promotional material -- stop right there.

MR. LIMBACHER: Object to form and foundation and further object as beyond the scope of the topics on which he's been designated.

THE WITNESS: I'm not sure of the specific records retention policies that pertain here, but I would -- I'm quite sure that Endo would have maintained whatever they are required to maintain, and, in my recollection, whenever I needed to see a piece of historic promotion, that was able to be provided, and that would be promotion that had ultimately been approved and in use. So I'm quite sure that anything that made it into commercial use, there was a

record retained of that.

BY MS. SCULLION:

Q. Okay. So is it your understanding, then, that in Exhibit 22 to the extent that Endo determined that we were citing to pieces in our request on topic 13 that were not final approved materials, that that's been indicated and that the remainder are, in fact, final approved materials?

MR. LIMBACHER: Object to form, foundation.

THE WITNESS: I think what you're asking is where it's noted that the claims were not used in final approved material, that that is indeed our position, that those claims did not find their way into a final piece of approved material.

BY MS. SCULLION:

Q. Right, and it's fair to say that the rest were --

A. I believe that in this chart there's a number of designations as to the specifics around the claims. One other is

important to note how they were used, for example, and by whom.

Q. Correct. Okay.

So if we could go to claim number 24, which is on page 9 of Exhibit 22. And in our request with respect to this claim, we cited to a document Bates stamped ENDO-CHI_LIT-00538441.

MS. SCULLION: And do we have that, it's E785?

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 23.)

BY MS. SCULLION:

Q. Let me hand you what's been marked as Exhibit 23.

And Exhibit 23 you'll see does bear that Bates number, correct, lower right-hand corner?

A. Yes, it does.

MR. LIMBACHER: And, counsel, just so we're clear, you've been asking him questions in his capacity as a 30(b)(6) witness?

MS. SCULLION: Yes, except to the extent that you've objected that it's beyond the scope. We'll have to see where that comes out.

BY MS. SCULLION:

Q. And you'll see in the chart we cite to certain statements in this document on pages 3 and 4, and if you turn in Exhibit 23 to page E785.3, you'll see on the right-hand side that is page 3.

Do you see that?

A. I see 785.3, yes, page 3, which is the column, right.

Q. Right.

A. The right-hand column, yep.

Q. All right. So before we get into specifics, if you can turn back to the first page of Exhibit 23.

Do you understand Exhibit 23 to be a copy of a brochure directed to patients?

A. By the date on the back, it's a 2006 piece of promotion, and I believe that that is provided to patients often by physicians. So these were often provided to physicians for

their selective use with patients that they deemed appropriate.

Q. It's your understanding that this is a 2006 document?

A. Well, that's the date on the back page.

MR. TOLIN: It says 2008.

THE WITNESS: I'm sorry. That's my glasses not working for me. It looks like 6 to me.

MS. SCULLION: I agree I think it's 2008.

BY MS. SCULLION:

Q. Okay. I'm sorry. But this is a brochure that was provided to patients, right?

A. Provided to physicians for their distribution to patients should they see the value in doing that.

Q. A document intended to go to patients eventually, right?

A. Correct.

Q. And you see the front cover at the bottom the logo for Promise Initiative?

A. I do, yes.

Q. And do you recall that the Promise Initiative was one aspect of how Endo sought to implement RiskMAP for Opana ER?

A. I'd have to look back at the RiskMAP document to remember explicitly what it was, because beyond that, I don't recall the Promise Initiative, specifically. I can refer back if you -- if that's important.

Q. Did you -- do you recall, though, that in RiskMAP one of the elements of RiskMAP was to create and distribute, among other things, patient brochures on taking long-acting opioids?

A. Yes.

Q. Okay. And this was one such brochure, right?

A. Yes.

Q. Okay. And if you'll try and hold both Exhibit 23 and 22 open at the same time, turning to page 3 of Exhibit 23 of the brochure, I just want to try and match up the language on the page with the language in the claims chart that is Exhibit 22.

Do you follow what I'm trying to

do?

A. Yes, I'm doing that in advance.

Q. And, in particular, the language that I want to focus in on is probably easiest to start with Exhibit 23 under the heading on page 3, "What is the risk of becoming addicted to a long-acting opioid?"

The answer is "Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

Did I read that correctly?

A. Yes, you did.

Q. And that language, in particular that last sentence, "most healthcare providers who treat patients with pain," that's part of the claim that we asked about in claim 24 in Exhibit 22, correct?

A. That's correct, yes.

Q. Okay. And with respect to that particular sentence on the right-hand side of

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the chart, it's called out, that particular sentence, and the citation is to "Definitions Related to the Use of Opioids for the Treatment of Pain, Consensus Statement of the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine."

Is that right?

A. Yes.

Q. And is that the sole support Endo cited at the time for the sentence most healthcare providers who treat patients with pain, et cetera?

MR. LIMBACHER: Object to form.

THE WITNESS: Yes, I believe that's the case in this particular -- the way that this is outlined, that's the support for the statement above. Statement above being pulled out of the claim to the left, I think that's correct.

BY MS. SCULLION:

Q. Okay.

A. That's the intention.

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Q. And then we've got a lot of moving pieces here.

MS. SCULLION: Can we have the definitions.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 24.)

BY MS. SCULLION:

Q. I hand you what's been marked as Exhibit 24.

A. Should I keep these open or nearby?

Q. It probably will be useful.

And Exhibit 24 is Bates stamped ENDO-OPIOID_MDL-06233148. Mark that down, Exhibit 24.

And Exhibit 24 is the definitions section cited in the claims chart we just looked at, right?

A. Yes.

Q. Okay. Just one second.

MR. LIMBACHER: Jen, just for the record, I want to object to any questions where you are showing him the

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supporting references and then asking him questions about what is in those supporting references. I believe Josh Davis made it very clear to you in his e-mail of January 6, 2019 that Mr. Lortie was not going to be prepared to speak as a corporate representative in full detail to all substantive or scientific aspects of all support that may be identified in this chart.

So if I can have a continuing objection to those types of questions where you're showing him the supporting references and then asking him to match that up with what's in the chart.

MS. SCULLION: I hear your objection. You can certainly have it on a continuing basis. I'd just note that our understanding was that although Mr. Lortie might not be prepared to sit here and parse in detail the scientific basis for any particular claim that's cited, that he was to be prepared to speak to the support for those claims.

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In fact, Mr. Davis made something of a point about the burden it would be for Mr. Lortie to be prepared on any additional claims because it had taken so much to prepare him to speak to the claims that we did have in the chart.

BY MS. SCULLION:

Q. If you will go to page 2 of Exhibit 24, you see under "Discussion" underlined there is the sentence, "Most specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders."

Did I read that correctly?

A. Yes, yes, you did.

Q. And is the little A next to that and the fact that it's underlined, is that an indication that that sentence is what is cited in support of the claim that we've been talking about from claim 24 from the brochure?

MR. LIMBACHER: Object to form,

same objection as stated previously.
THE WITNESS: I'm not sure about the underlining and the A, but if I read that sentence and I see that that's raised as a support -- piece of support for that, I think that that's what the intent is.
BY MS. SCULLION:
Q. And the sentence in the definitions that's slated as support for the sentence in the brochure is then followed, though, by another sentence, an important qualifier to the first sentence, right?
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. The second sentence says, "However the actual risk is not known and probably varies with genetic predisposition, among other factors."
And the next sentence, "Addiction, unlike tolerance and physical dependence, is not a predictable drug effect."
Do you see those two following sentences?

A. Yes, that's part of the second sentence, but, yes, I read that it follows.
Q. Okay. Now, you would agree in the brochure, though, there is no such additional information that qualifies the statement "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," right?
MR. LIMBACHER: Same objections.
THE WITNESS: It's correct. The claim is written down and the support is what's cited, but there's no additional qualifier.
BY MS. SCULLION:
Q. And so the claim is really only pulling from part of what the definitions in the consensus statement said with respect to the risk of becoming addicted to a long-acting opioid, right?
MR. LIMBACHER: Same objections.
THE WITNESS: There are many paragraphs that follow the cited reference so --

BY MS. SCULLION:
Q. Right.
A. -- you're correct, the authors did not lift the entirety of the definitions as the claim or as support.
Q. Right.
So, I mean, the brochure in answering this question, this important question for patients, "What is the risk of becoming addicted to a long-acting opioid" only cited part of the answer to that question provided in the definitions of the consensus statement, right?
MR. LIMBACHER: Object to form.
THE WITNESS: What I can say to that is that the medical, legal, regulatory professionals who signed off on this felt that that was adequately cited and supported to the extent that it was put forward in a piece of promotion.
BY MS. SCULLION:
Q. But you would agree, reading this, the brochure only tells, at best, half the

story?
A. No, I wouldn't agree with that. I think that there's many paragraphs that follow and that the medical professionals who signed off on that as an appropriate piece of -- appropriate citation to support the statement felt that that was adequate and well balanced, and it's not my role to question that.
Q. So you don't think just, you know, putting aside, you know, whether it was your role within Endo to look at these promotional materials, because that wasn't your role at the time, right?
A. That's correct.
Q. You don't think just as an average person looking at a brochure directed to patients with respect to inherently dangerous and risky medications like Opana ER and other long-acting opioids that it would be inappropriate to only answer that "most healthcare providers who treat patients agree that patients treated with prolonged opioid medicines usually do not become addicted" and then not explain that the actual risk is not

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known and probably varies; you don't think a patient should know the actual risk is not known?

MR. LIMBACHER: Object to form and object to the extent it's outside the scope of the topics on which he's been designated as agreed to by counsel.

THE WITNESS: And, first of all, I should point out that I do not agree with your characterization of Opana ER as an inherently dangerous medicine. It was safe and effective when used as directed. But going on, my answer remains the same, the medical professionals, whose job it was to determine whether or not the support was adequate, signed off on this, and it's not my place either today or back then to double -- to second-guess that.

BY MS. SCULLION:

Q. So whatever they signed off on is good enough for you; you're not going to second-guess it?

MR. LIMBACHER: Object to form.

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THE WITNESS: I trust the policy and I trust the FDA who had review rights on any piece of promotion that we put out. Endo never, to my knowledge, received a warning letter back from the FDA, so I think our policy worked.

BY MS. SCULLION:

Q. So just because the FDA never caught it and issued a warning letter, that means it was okay?

MR. LIMBACHER: Object to form, misstates his testimony.

THE WITNESS: I think that's an important consideration.

BY MS. SCULLION:

Q. So you don't think that a patient should know the actual risk of addiction in using long-acting opioids was, in fact, unknown?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not answering -- I'm not agreeing to that statement. What I'm saying is that the support for the statement and the claim, as indicated here by this -- by the

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citation was adequate for our medical, legal and regulatory professionals, and I'm not going to second-guess that.

BY MS. SCULLION:

Q. And within the definitions, there's no actual data cited here for this proposition that most specialists in pain medicine, addiction medicine agree that patients treated with prolonged opioid therapy usually do not develop physical dependence -- usually do develop physical dependence and sometimes develop tolerance, but do not usually develop addictive disorders, there's no actual citation to any survey or study or anything there, right?

MR. LIMBACHER: Object to form. The document speaks for itself.

THE WITNESS: I think by its definition, it is a consensus statement by knowledgeable bodies who are learned in the field, and it's not a statement that would normally be supported by specific clinical data. That normally would be product A has this effect on pain or product B has this effect on

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blood sugar levels. That's not what's being stated here. This is a consensus statement, a definition and it's cited appropriately.

BY MS. SCULLION:

Q. Well, the statement, though, is attempting to quantify the level of agreement about the level of risk of addiction to long-acting opioids, right?

MR. LIMBACHER: Object to form.

THE WITNESS: Again, it's a consensus statement. By definition, it is what it is.

BY MS. SCULLION:

Q. But it's a statement about quantification, correct, quantification of how many providers agree and what they agree about in terms of the level of risk, right?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm not sure I agree with that, no.

BY MS. SCULLION:

Q. Well, when it was cited as support for the statement in the patient

brochure, the statement in the patient brochure was specifically in response to a question that asked to quantify the risk of becoming addicted to a long-acting opioid, right? So, again, this is a statement about quantifying a risk, right?

MR. LIMBACHER: Object to form, misstates the document.

THE WITNESS: And I don't know what you mean by "quantify." To me quantify means citing a numerical response. It's saying what is the risk. It's not saying is the risk greater than or equal to X or Y.

BY MS. SCULLION:

Q. Right.

So but what is the risk is something that you would quantify, right? Is it a low risk? Is it a high risk? Those are quantifications of risk, correct?

MR. LIMBACHER: Object to form, compound question and asked and answered.

THE WITNESS: Yeah, I think we've answered that. I mean, it's a consensus

statement by a number of bodies who are expert in the field, and it's cited appropriately to support the statement.

BY MS. SCULLION:

Q. Going, though, back to the brochure that was intended to be provided to patients, this is intended to answer to them -- for them the question of what is the risk of becoming addicted to a long-acting opioid. Don't you agree that the average patient reading that would understand that the answer was quantifying for them what the relative level of risk was of becoming addicted to a long-acting opioid?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I think that the support here, in my view, and in the view of our medical professionals or those who were in place in the 2008 period felt that this was adequate support, and I don't know what else I can say.

MS. SCULLION: Move to strike.

That was not the question.

BY MS. SCULLION:

Q. The question is don't you think the average patient getting this brochure is going to read that question and understand that this brochure is attempting to answer for them how to quantify the risk of becoming addicted to a long-acting opioid?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I'm not sure that's true. That's not how I read this.

BY MS. SCULLION:

Q. What else does it mean when the question is "What is the risk of becoming addicted to a long-acting opioid?"

MR. LIMBACHER: Object to form.

THE WITNESS: I think the company attempted to answer that risk by citing the consensus statement.

BY MS. SCULLION:

Q. Well, but the company didn't cite the consensus statement, right? It didn't cite the consensus statement by name here in the

brochure, and we've already established the company did not, in fact, put in the complete answer, even in the consensus statement definitions, to that question, correct?

MR. LIMBACHER: Object to form. Which question would you like him to answer?

THE WITNESS: No, I don't agree with that. Again, if the company -- if what you're saying is the only appropriate action on behalf of the company would have been to send the consensus statement to the patient, I would contend that that would be very unhelpful and uninterpretable by the patient.

There's a claim made. It passes through the legal, medical and regulatory process, and it is cited by a consensus statement.

BY MS. SCULLION:

Q. You understand that the part of this lawsuit, though, is about whether, in fact, those claims, despite having passed through the

process, were supported, right?
MR. LIMBACHER: Object to form, foundation.
THE WITNESS: I understand that that's the topic that we're talking about here.
BY MS. SCULLION:
Q. Right.
And so trying to understand whether, in fact, despite it having passed through the process at Endo, was it fairly supported, and in response to this question for patients, "What is the risk of becoming addicted to a long-acting opioid," Endo did not put in the brochure that the actual risk is not known, didn't tell the patients that important fact, right?
MR. LIMBACHER: Object to form, asked and answered.
THE WITNESS: The claim is -- the claim that's in the brochure, we can read the claim and we can read the supportive documentation, and the medical professionals and the legal and

regulatory professionals felt that that was adequate, and I'm not in a position to defend that or contradict that. That was their job. That's the job of the process, and it's the company's contention that that was adequately supported.
BY MS. SCULLION:
Q. And we know that that process, though, resulted in a brochure that did not, in fact, tell patients the actual risk is unknown, right?
MR. LIMBACHER: Object to form.
BY MS. SCULLION:
Q. Didn't tell them that?
MR. LIMBACHER: Foundation, outside the scope of the topics on which he's been designated.
BY MS. SCULLION:
Q. Doesn't say it, right?
A. Those words are not in there.
Q. That's right.
A. But it's -- the significance of that I'm not sure what we can agree on.

Q. Now, in the consensus statement is a consensus statement, if you go to page 3 of Exhibit 24, consensus statement of the American Academy of Pain Medicine, correct?
A. Sorry. Let me just catch up here.
Q. Sure, the bottom of page 3.
A. It's actually in the middle of page 3, I think, right?
Q. I'm looking at the page that's labeled in the lower left-hand corner 3 of 4, and underneath it says the date on which it was approved by the AAPM Board of Directors, February 13th, 2001.
Do you see that?
A. Okay. I'm sorry I was on the cover where the three organizations were listed. I think they're probably the same ones, but so I'll go to your page.
Q. Let's -- I want to go -- be specific on page 3 of 4, you see after the definitions it says "Approved by the AAPM Board of Directors on February 13, 2001."
A. Yes.

Q. And the AAPM is American Academy of Pain Medicine, right?
A. Yes.
Q. And the American Academy of Pain Medicine was recognized as the industry-friendly organization, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't know. I don't know that.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 25.)
BY MS. SCULLION:
Q. Let me hand you what's been marked Exhibit 25. And Exhibit 25 is Bates stamped ENDO-CHI_LIT-00051623, and we stamped it E1605 at the top right-hand corner.
And, Mr. Lortie, you see on the cover of E-25 is an e-mail at the very top from David Lee to Nancy Santilli in September of 2010 attaching a copy of the Issues Management Strategy developed prior to launch of Opana ER.
Do you see that?
MR. LIMBACHER: Take your time

and read the document.
THE WITNESS: I see the e-mail, yes.
BY MS. SCULLION:
Q. Okay. And then just going to the attachment to the e-mail, looking at the very first page of the attachment entitled "Public Stakeholder Strategy for Oxymorphone."
Do you see that?
A. I'm sorry I'm still on the e-mail trying to make sure I understand the context.
Q. Sure.
A. Now I'll take a look through the slide deck.
Q. Sure. Just to orient you, the first page of the slide deck, it's up here on the screen, "Public Stakeholder Strategy for Oxymorphone."
Do you see that?
A. Yes.
Q. It was prepared for Endo Pharmaceuticals by its consultant Michael Bolen, correct?
A. I assume the date field is one of

these that automatically updates, because I don't think this was created three or four days ago.
Q. Yeah, if you're talking about the date in the lower left-hand corner 1/21/2019, yes, our understanding is that date populates automatically when we print the document.
A. We'll -- this was back in 2010 so apparently --
Q. Actually, according to the e-mail, it was forwarded on to Nancy Santilli in September of 2010, but Mr. Lee explains that it was developed prior to launch of Opana ER.
Do you see that?
A. Thank you. Yes, I do. That's helpful.
Q. Okay. And then if you go within the Public Stakeholder Strategy for Oxymorphone document, if you go to page 6 of the document.
MR. LIMBACHER: Take your time, review the document.
BY MS. SCULLION:
Q. You see it's entitled -- I'm sorry, I think it's -- yeah, this one.

"Prioritize Outreach to Third Party Groups -- Select Tier One Advocates."
Do you see that?
A. I'm not quite there yet. Give me a moment, if you would.
Q. Sure.
A. Okay. And you were pointing me to page 6, I believe?
Q. Yes, page 6 explains to "Prioritize Outreach to Third Party Groups -- Select Tier One Advocates."
Do you see that?
A. Yes.
Q. And then it explains the criteria for being selected as a tier one advocate includes -- let's look at the third bullet point, "Strong focus on promoting improved patient and/or provider access to pain management."
Did I read that correctly?
A. I see that, yes.
Q. All right. And then if you go to page 15 of the deck, you'll see it identifies as a "First Tier," so meeting those criteria,

"Professional Pain Management Advocacy Organizations," and here it's listed the "American Academy of Pain Medicine," and that was the same organization that was one of the organizations approving of the consensus statement we were examining, correct?
MR. LIMBACHER: Object to form, and I would object to the extent these questions fall outside the scope of the topics on which he's been designated.
THE WITNESS: Sorry, question?
BY MS. SCULLION:
Q. It's the same organization, right, the American Academy of Pain Medicine, and that's the same organization that signed off in part on the consensus statement, right?
A. They were -- yes, that's one of the organizations cited within the consensus statement, correct.
Q. And on this page, third bullet point, Endo's consultant explains one of the reasons that American Academy of Pain Medicine is identified as a first tier advocacy organization is that it is "industry friendly,"

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correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I see that written there, yes.
BY MS. SCULLION:
Q. And under that it says "Endo advisors and speakers bureau active members."
Do you see that?
A. I do, yes.
Q. And the speakers bureau were -- was a effort by Endo to have various healthcare providers who would go around and speak to physicians and other providers about Endo's products, correct?
MR. LIMBACHER: Object to form and object to the extent it's beyond the scope of the topics on which he's been designated.
THE WITNESS: Speakers bureaus by definition are used by companies, Endo and others, to provide scientific information and background in a variety of different venues.
BY MS. SCULLION:

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Q. And they're paid by Endo to do that; they were when you were there?
A. Well, from time to time. I mean, typically, speakers bureaus are compensated, as are scientific advisors and often there's overlap.
Q. Right.
So both advisors and speakers bureau participants would be compensated by Endo, correct?
MR. LIMBACHER: Object to form and, again, object as beyond the scope of the topics on which he's been designated.
THE WITNESS: Yeah, I mean, in general, but in this context I don't know specifically how Endo advisors and speakers bureau active members relates to the American Academy of Pain Medicine, so I can't agree to that statement. I don't know that to be the case.
BY MS. SCULLION:
Q. It says -- it's referring to the

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fact that Endo advisors, Endo paid advisors and Endo paid speaker bureau participants were also active members in this industry friendly organization; that's what it's saying, right?
MR. LIMBACHER: Same objections.
THE WITNESS: Yeah, I'm not sure that's what it's saying.
BY MS. SCULLION:
Q. Okay.
A. I will also say, though, on slide number 6 where you pointed me earlier, one of the key criteria for a tier one advocate was that it was respected and credible, so I just wanted to point that out. That's also important. Consensus statements are not written to benefit any company, they're written to stand alone and be supported by evidence, and I just want to make that point.
Q. Right.
But in addition to being respected and credible, because there's other organizations that are respected and credible, to be an actual tier one advocate, there had to be a strong focus on promoting improved patient

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and/or provider access to pain management, correct?
MR. LIMBACHER: Object to form and, again, object as outside the scope of the topics on which he has been designated.
The subject of Endo's relationship with the American Academy of Pain Medicine is specifically referenced in topic number 36 of your 30(b)(6) deposition notice, and this witness has not been designated to testify with regard to topic number 36.
MS. SCULLION: Counsel, objection to beyond the scope is just fine. I think you're now crossing a line to try to coach the witness.
MR. LIMBACHER: I'm not coaching the witness.
MS. SCULLION: It's -- it is beyond --
MR. LIMBACHER: I'm trying to gently suggest to you, counsel --
MS. SCULLION: Counsel, if you

let me finish my statement, I let you finish yours.

MR. LIMBACHER: -- that you are asking questions that go well beyond the scope of what you know this witness has been designated for.

MS. SCULLION: And you know that we asked for this witness both with respect to his 30(b)(6) topics and in his personal capacity. If it is indeed beyond the topic, which I don't agree, he's perfectly welcome to answer the questions in his personal capacity.

MR. LIMBACHER: Well, you're not going to get 14 hours of questioning of this witness in his individual capacity. You have to make a decision as to whether or not you're asking him questions in his role as a 30(b)(6) witness or not. We have an agreement that we memorialized at the outset of this deposition that unless you make it clear that you are asking him questions about 30(b)(6), then he's answering

these questions in his role as a fact witness, but you have told us that all of the questions with regard to this chart are in his capacity as a 30(b)(6) witness, but the questions you are now asking with regard to the American Academy of Pain Medicine fall well outside the scope of the topics on which he has been designated and, in fact, are specifically referenced in topic 36.

MS. SCULLION: Right, so we disagree. I think they're also encompassed within topic 37. I suggest we just -- you just say object to the scope and we deal with it at some other time if needed, but let's -- I think we should move on with the testimony.

BY MS. SCULLION:

Q. And then one of the other organizations, going back to Exhibit 24, which is the definitions and consensus statement, one of the other organizations that approved the definitions that you've cited was the American Pain Society, and that's at page 3 of 4 of

Exhibit 24, correct?

A. I'm looking for that.

Q. Sure. At the very bottom underneath the approval by the AAPM, you next have approved by the APS Board of Directors.

Do you see that?

A. And then under that it says American Pain Society, correct?

Q. Correct.

MR. LIMBACHER: Same objections, counsel. And, again, American Pain Society is specifically referenced in topic 36.

BY MS. SCULLION:

Q. And then if you go back to Exhibit 25, you also see that American Pain Society is also identified as a tier one advocate, and that is at -- if you go to page -- where we were -- page 15, it says "First Tier Professional Pain Management Advocacy Organizations," right, so it's going to be listing multiple organizations. The first one we've been through the American Academy of Pain Medicine.

Go to the next page, the next of those first tier professional pain management advocacy organizations is the American Pain Society, correct?

MR. LIMBACHER: Same objections, beyond the scope.

THE WITNESS: On top of page 16, I see "American Pain Society," yes.

BY MS. SCULLION:

Q. Okay. And if you go back to Exhibit 24, I think we've seen before that the AAPM, American Academy of Pain Medicine and the American Pain Society as well as the American Society of Addiction Medicine signed off on this definition as of February of 2001, correct? That's what it says?

A. That is what it says, yes.

Q. Okay. And as of that time, February of 2001, Endo had paid each of the AAPM and the APS tens of thousands of dollars, correct?

MR. LIMBACHER: Object to form, foundation, beyond the scope of the topics on which he's been designated.

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THE WITNESS: That predates me by many, many years. I have no idea what Endo's funding policies or practices were in 2001.
BY MS. SCULLION:
Q. During the time that you were with Endo, you were aware that Endo paid each of those organizations certain monies?
A. No, not specifically.
MR. LIMBACHER: Object to form and foundation, beyond the scope of the topics on which he's been designated.
BY MS. SCULLION:
Q. With respect to the payments as of 2001, I won't burden the record here, but I would note that they're specifically identified in, among other places, Endo's July 2012 -- yeah, June 2012, June 15, 2012 submission to Senators Max Baucus and Charles Grassley in connection with their inquiries into the promotion of opioids.
MR. LIMBACHER: Same objections and move to strike.
BY MS. SCULLION:

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Q. Now, if we go back to the brochure, back to Exhibit 23, the brochure. Looking at the language there, "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." That's an indication at least -- sorry, that's a representation of some level of agreement that the risk of addiction to -- from the use of opioids for chronic pain is low, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Can you ask a question? You made a statement there.
BY MS. SCULLION:
Q. I'm asking that's -- it's a representation of --
A. What's the question?
Q. -- an agreement that the risk of addiction from the use of opioids in treatment of chronic pain for prolonged use, let's put it that way, is low?
MR. LIMBACHER: Object to form.
THE WITNESS: Yeah, I disagree. Again, it goes back to our previous

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discussion on quantification. I think the statement stands on its own.
BY MS. SCULLION:
Q. What does "usually do not become addicted" mean if it doesn't mean that it's low?
MR. LIMBACHER: Object to form.
THE WITNESS: But I don't know what low means in this case, so I'm not prepared to quantify that.
BY MS. SCULLION:
Q. Would you agree that it means most of the time it does not occur, usually do not become means most of the time not?
MR. LIMBACHER: Object to form and beyond the scope of the topics on which he's been designated.
BY MS. SCULLION:
Q. Would you agree with that?
A. Would I agree with what?
Q. That usually do not become addicted mean most of the time does not become addicted, that's the representation?
MR. LIMBACHER: Same objections.
THE WITNESS: I think that that's

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fair.
BY MS. SCULLION:
Q. And you're aware that the FDA specifically struck such language from Endo's label for Opana ER, correct?
MR. LIMBACHER: Object to form, foundation, beyond the scope of topics for which he's been designated.
THE WITNESS: I'm not aware of that specifically, no.
MS. SCULLION: Okay. Can we have the binder of labels. Can we mark these as the next four exhibits.
(Documents marked for identification as Endo-Lortie Deposition Exhibit Nos. 26, 27, 28 and 29.)
BY MS. SCULLION:
Q. I'm going to hand you a binder with exhibits that have been marked Exhibits 27 --
A. Mine starts with 26.
Q. Twenty-six, that's what I got wrong, thank you, 26, 27, 28 and 29.

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And let's start with Exhibit 26, which is Bates stamped ENDO-OPIOID_MDL00291042, and we've marked it in the upper right-hand corner E1407.1.

Mr. Lortie, do you recognize this as Endo's Application Summary for oxymorphone extended release ER tablets, and then there's a code name EN3202 dated November 23rd, 2005?

MR. LIMBACHER: And, counsel, at this point, are we asking him questions in his capacity as a fact witness or as a 30(b)(6) witness?

MS. SCULLION: As a 30(b)(6) witness.

MR. LIMBACHER: And under what topic are you asking him these questions?

MS. SCULLION: These all go to topic 13.

MR. LIMBACHER: I'm sorry?

MS. SCULLION: Topic 13.

MR. LIMBACHER: I would object to questions with regard to labeling as being outside the scope of what he has

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been designated for on topic 13.

MS. SCULLION: So on topic 13 it goes to the support for the statements in the brochure because, as we understand, those were specifically prohibited by the FDA, and that's why the labeling history will show that, just to give the connection.

MR. LIMBACHER: And my objection stands.

BY MS. SCULLION:

Q. Do you recognize Exhibit 26 as that application summary by Endo?

A. I read that's what the title is. This is not a document I would have referred to or seen in the normal course of my time there, so I don't recognize it, but the title suggests that it is what you represent.

Q. Okay. If you go to page E1407.18 under the heading "Misuse, Abuse and Diversion of Opioids."

A. Yes.

Q. Oh, I'm so sorry I think I misspoke. It's 1407.18?

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A. That's what you said.

Q. Thank you. The screen was not caught up. That's okay. I think I spoke a little too quickly.

A. I'm looking at the book, not the screen.

Q. Under "Misuse, Abuse and Diversion of Opioids," the fourth paragraph down, do you see that Endo said in its original -- in its submission here, second and third sentences, "The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients."

Do you see that?

MR. LIMBACHER: Object to form and foundation, and, counsel, can I have a continuing objection to questions with regard to Exhibits 26 through 29 as being outside the scope of the topics on which he's been designated as a 30(b)(6) witness?

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MS. SCULLION: Sure.

MR. LIMBACHER: Thank you.

THE WITNESS: Yes, I read that paragraph.

BY MS. SCULLION:

Q. And those sentences are similar to what we saw in the consensus statement definitions, Exhibit 24, correct?

A. I'm not sure I agree. I mean, we can look back at that if you want to parse it specifically.

Q. That's okay. I think we've gone through that in enough detail already.

But you would agree, though, that as of the date of this submission, Endo agreed that data are not available to establish the true incidence of addiction in chronic pain patients? That's what Endo told the FDA in this submission, right?

MR. LIMBACHER: Objection, form and foundation.

THE WITNESS: That's what's represented here in the paragraph in this submission, yes.

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BY MS. SCULLION:
Q. And then if you go to Exhibit Number 27, which is next in your binder, and it's Bates stamped ENDO-OPIOID_MDL-00299099, in the upper right-hand corner we've labeled it E1408.
Do you see this is a letter from Bob Barto, senior director regulatory affairs, to Dr. Bob Rappaport at the FDA dated June 30th, 2006?
MR. LIMBACHER: Same objections as stated previously.
THE WITNESS: I see that.
BY MS. SCULLION:
Q. And the second paragraph do you see that Mr. Barto references an e-mail from Lisa Basham, regulatory health project manager, I'll represent to you she is from the FDA, to Mr. Barto, and he says, "In the aforementioned e-mails, Ms. Basham-Cruz relayed the following request from the Division," and then he has text that carries over to the next page, E1408.2, and do you see the second full paragraph on 1408.2 has the text we were just looking at in Endo's

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original labeling submission, but the FDA has asked for both of those sentences to be crossed out and removed from the label, correct?
MR. LIMBACHER: Objection, form and foundation, beyond the scope and predates his employment at the company.
THE WITNESS: Yeah, that language is struck. This is a CBE 30, a changes being effective. What I don't know, and I don't know where this lies with regard to the initial marketing of the product, or my other question is to what extent is the agency asking for alignment to the -- the labeling that's exactly similar across opioids. So those are a couple questions I can't answer that with this in front, but those are questions that are raised.
So I don't know if the agency struck this to make sure that the Opana label before use for the first time was in align to category-wide labeling or if it was done in some other correspondence. We don't have the

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actual correspondence to refer to, but anyway.
BY MS. SCULLION:
Q. But you would agree, though, that the agency, the FDA did specifically strike from the initial labeling submission the statement that "the development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare," that was stricken, right?
MR. LIMBACHER: Objection, form and foundation and beyond the scope.
THE WITNESS: Correct. They struck those last sentences in that paragraph.
BY MS. SCULLION:
Q. Okay. And on the assumption that the agency never changed that position, you would agree that Endo could not make assertions in its promotional materials that the development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare, couldn't make that statement, right?

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MR. LIMBACHER: Objection, form and foundation and beyond the scope.
THE WITNESS: Well, I think it would depend on when they made the statement, what the language in the label was that was then current at that time, that would be important for the group to refer to when they approved such use of such a claim.
BY MS. SCULLION:
Q. But if the FDA never approved that language, you couldn't then say it in promotional materials, for example, right?
MR. LIMBACHER: Same objections.
THE WITNESS: The important thing to consider is labeling changes over time, so it's the label that's in effect at that moment that defines and supports whether or not a given claim can be made. So I can't draw that conclusion for 2008 piece from this. It may be true, but it also may not be.
BY MS. SCULLION:
Q. But if it was, in fact, true that

in the label in effect as of the June 10 -- the 2008 piece that it did not include language with respect to the development of addiction being reported to be rare, that Endo should not be saying that the risk of addiction is rare, right?

MR. LIMBACHER: Same objections.

THE WITNESS: Yeah, but you're asking me to speculate on what the label was at the time, and, also, I'm not a regulatory, medical or legal professional, so we left those determinations to be made by the team that -- whose job it was to do that.

MR. LIMBACHER: Are we at a good stopping point?

MS. SCULLION: Yeah, we can stop there.

MR. LIMBACHER: Thank you.

THE VIDEOGRAPHER: The time is 4:43. We're going off the record.

(Brief recess.)

THE VIDEOGRAPHER: The time is 5:00 p.m. We are now back on the

record.

BY MS. SCULLION:

Q. Mr. Lortie, welcome back. I'm going to ask you some questions in your personal capacity.

A. Okay.

Q. Sure is good news to counsel's ears at this point.

Mr. Lortie, when you were with Endo, you recall that Endo -- sorry, Endo sought FDA approval for a reformulated version of Opana ER?

A. Correct.

Q. And Endo initially sought approval for claims that the reformulated version of Opana ER was crush resistant, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: That's correct.

BY MS. SCULLION:

Q. Okay. And the FDA did not grant the claim of crush resistance, correct?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: Not necessarily. The FDA responded to the submission of the material and accepted certain claims and certain language and asked us not to use other language. We made appropriate revisions with the -- then sent FDA the material as per the requirements and put the revised version into use.

BY MS. SCULLION:

Q. Did Endo allow its sales reps to describe the reformulated version of Opana ER as crush resistant?

MR. LIMBACHER: Object to form, foundation.

THE WITNESS: The specific language that was used for a period of time upon agreement, you know reflection on the FDA's comments and, again, through our medical, legal and regulatory review process was designed to be crush resistant. That was the language that was used.

BY MS. SCULLION:

Q. Right.

And sales reps were specifically instructed not to describe the reformulated version of Opana ER as crush resistant but to use the specific phrase designed to be crush resistant, right?

MR. LIMBACHER: Object to form.

THE WITNESS: The way it was represented was designed to be crush resistant, and then every time that was used, there was also a prominent warning that said the -- and I'm parsing the words here, but the degree to which that conferred abuse resistance has not yet been determined.

BY MS. SCULLION:

Q. Right.

So it was Endo agreed that it did not yet have data to show that the reformulated version of Opana ER was abuse deterrent, right? That's why it had that qualifying language, correct?

MR. LIMBACHER: Object to form, foundation.

THE WITNESS: Just to be

accurate, the data was in evolution. We had not yet submitted that data to the FDA and had FDA's endorsement of a label change, very long process, very well-defined. So we were developing that data in real time, of course, until that was approved by the agency, no label change could be made.

BY MS. SCULLION:

Q. Right.

And no promotion of reformulated Opana ER could be made that it was abuse deterrent until the FDA had approved that, right?

MR. LIMBACHER: Object to form.

THE WITNESS: Until the FDA would have allowed label claims as to the clinical relevance of the design to be crush resistant, it was just simply designed to be crush resistant with the disclaimer that said the degree to which that confers abuse resistance has not been determined.

BY MS. SCULLION:

Q. Right.

And so to circle back then, the product could be described as designed to be crush resistant, but it could not be described as crush resistant?

MR. LIMBACHER: Object to form.

THE WITNESS: My recollection is designed to be crush resistant, but could not be described as having abuse deterrent relevance at that point, given that the data had not been submitted.

BY MS. SCULLION:

Q. Well, could Endo have described the reformulated version of Opana ER in its promotional materials as just crush resistant? Could it have used that phrase without designed to be?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. Is that permitted?

MR. LIMBACHER: And foundation.

THE WITNESS: We didn't submit that to the agency, to my recollection. We landed on the designed to be crush resistant because we felt that that provided important information to physicians who wanted to know what was the difference between the new and the old and recognizing that there was going to be a period of time where the clinical trial to hopefully bring about the abuse deterrent language was in process, so designed to be crush resistant with the prominent disclaimer was where the company landed, and that's what was put into commercial use.

BY MS. SCULLION:

Q. And FDA had never signed off of on just the phrase crush resistant, right?

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. Just had never signed off on that?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I don't recall specifically. I don't know that we had ever asked them just to sign off on that.

They had seen the designed to be crush resistant in a submission, and they allowed that to go forward, but crush resistant as a stand-alone was never used as a stand-alone, no, claim.

BY MS. SCULLION:

Q. I'm sorry, so this really is a yes or not question. The FDA did not ever sign off on just the phrase crush resistant, right?

MR. LIMBACHER: Object to form, and he responded by saying I don't recall specifically. It is not a yes or no question, counsel. Object to form and foundation, asked and answered.

THE WITNESS: Yeah, again, just to be clear, I don't recall us ever asking them to sign off on that.

BY MS. SCULLION:

Q. Right, I understand that you don't recall ever asking. So did FDA -- do you know whether FDA ever signed off on the phrase crush resistant?

MR. LIMBACHER: Object to form

and foundation, asked and answered.
THE WITNESS: If my position is that I don't recall us even asking them, how can I know if they -- how can I answer that they never did? I don't believe we ever asked them that as a stand-alone. We certainly never put that in use as a stand-alone. So to answer whether or not they allowed that, I don't have a ground -- I don't have a basis to answer that question.
BY MS. SCULLION:
Q. And, as you said, Endo decided to use the phrase designed to be crush resistant to describe reformulated Opana ER, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Yes, that again always accompanied by the appropriate disclaimer. That was what we put into use.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 30.)
BY MS. SCULLION:

Q. Okay. Let me show you what's been marked as E14 -- I'm sorry, Exhibit 30.
Exhibit 30 is Bates stamped ENDO-CHI_LIT00206530, and it's stamped in upper right-hand corner E1497.
And do you recognize Exhibit 30 as an e-mail chain, which includes an e-mail from you to Kristin Vitanza dated May 15th, 2012 concerning the new language for the OER selling piece?
MR. LIMBACHER: Take your time and review the document.
THE WITNESS: You said 1497, correct?
MS. SCULLION: Yeah.
THE WITNESS: So let me just take a look from the beginning to orient myself.
(Witness reviews document.)
Okay. Thank you. I've reviewed it.
BY MS. SCULLION:
Q. Okay. And Exhibit 30 is an e-mail chain that concerns designing a selling

piece for reformulated version of Opana ER using the phrase designed to be crush resistant, right?
A. Yes, that's correct.
Q. And Ms. Vitanza is writing concerning the MARC review process for such a piece, correct?
A. She references that among other things, yes.
Q. And you say to her in your e-mail at the top of page E1497.1, in terms of the MARC review process for such a piece, "I suggest accelerating and going straight to escalation," correct?
A. Yes.
Q. So you were advising her to have an accelerated MARC review for this piece, correct?
A. No, no, that's not what it's saying.
Q. What does -- what did you mean by "I suggest accelerating and going straight to escalation"?
A. In order -- as I read through the

memo here, there was a desire to have a piece ready for an upcoming sales meeting, so for training on the sales meeting. Kristin's earlier e-mail suggests that it may be difficult to get that into the normal MARC review schedule because certain people were out of the office.
So one of the opportunities to get the -- get something in that circumstance reviewed is to go right to escalation, which means the next level up in terms of medical, regulatory would review on behalf of their team, and I think that's what we're asking for here is my endorsement to go straight to escalation so that we can get this reviewed by senior medical, legal regulatory in time hopefully to make the meeting.
Q. As you say, so the suggestion was to take this outside the normal MARC review process, instead use the accelerate to escalation as you've recommended, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: No, it's not outside of the normal process. The escalation and that capability is part

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of what's allowed within the normal process in certain circumstances. So it's not circumventing or going outside of the approved process. It's simply using an ability, from what I recall here, to get it, get this piece reviewed on time.

BY MS. SCULLION:

Q. You said, you testified in response to the prior question that Kristin said it may be difficult to get that in the normal MARC review process, and so you were suggesting the escalation. So you're contrasting escalation to the normal non-escalated MARC review process, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Escalation then as distinct from non-escalation, but my point is that escalation is part of acceptable MARC -- in this case MARC review policy and procedure in certain circumstances. It's not circumventing the controls or the normal medical, legal, regulatory review. It's just

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doing it in a way that gets it done on time in this particular case, and there was provisions made for that for circumstances just like this.

MS. SCULLION: Let's look at what's been marked as Exhibit 31.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 31.)

BY MS. SCULLION:

Q. And Exhibit 31 is Bates stamped ENDO-CHI_LIT00110100, and we've marked it E1482 in the upper right-hand corner.

A. Yes.

Q. And you'll see in Exhibit 31, which is discussing that the same issue of the process for review of a sale piece in advance of the upcoming -- it says POA meeting, is that plan of action meeting?

A. Yes.

Q. And the top third of the page, you see the e-mail from Marv Kelly to Kristin on May 15th at 10:23 a.m.?

A. Yes, I see that.

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Q. Right, and who was Marv Kelly at that time?

A. Marv was the marketing vice president at that time.

Q. Okay. And Mr. Kelly is saying to Kristin Vitanza in the first paragraph of his e-mail, "I know a MARC review outside of normal schedules will be required" in order to get the piece available for the POA, correct?

A. That's what he writes, yes.

Q. Right, so, again, so he's suggesting at least an accelerated schedule for the MARC review, correct?

A. Yes, an accelerated schedule.

Q. And he explains, goes on to explain, "I'm going to rally all levels of the organization to make this happen. We have no greater priority."

Did I read that correctly?

A. That's what he wrote, yes.

Q. So this is the VP of marketing who is the senior-most executive within at least the marketing department at that point, correct?

A. Correct.

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Q. And he is dictating that the MARC review process for this piece is going to have -- he will make it happen on an accelerated basis, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: He's not saying that he's going make MARC happen. He's requesting an accele -- he's requesting a outside of normal schedule MARC process, which as vice president of marketing he has the ability to request, but he's not -- as marketing VP, despite his seniority, he does not have the ability to make the MARC review do anything unusual. This is all within normal process. There are -- as I said before, there are provisions for things that needed to be done outside of normal schedules.

BY MS. SCULLION:

Q. And then but he is indicating to everyone that we have no greater priority than to conduct a review of this piece, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: He wrote that. He's indicating his view on the importance of having this done.
BY MS. SCULLION:
Q. Now, this is in May of 2012, correct?
A. May 5th, in fact, yes.
Q. Yes. And reformulated Opana ER had been approved in the end of 2011, correct?
A. Approval was December of 2011.
Q. Right. And there was no specific regulatory requirement that Endo had to proceed with a commercial launch of the reformulated version of Opana ER by any particular date in May or June of 2012, right?
MR. LIMBACHER: Object to form.
THE WITNESS: Correct. The FDA does not have an opinion on when something gets launched, other than that it be after its approved.
BY MS. SCULLION:
Q. Okay. This was just Endo's decision that it wanted to move forward as quickly as possible with review of this piece in

order to try to have it for a launch in June, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm not sure that's true. It's the upcoming plan of action meeting. I don't believe we saw with the data that it was going to be. That appears to be the timing or driving the timing.
BY MS. SCULLION:
Q. Right.
But there was nothing that required Endo to have the selling piece available for that meeting, right? Endo could have waited and done an ordinary course MARC review of the piece, right?
A. Well, what I read here is in the opinion of the marketing vice president, that it was important to have a piece, if approved, ready to take advantage of the fact that the sales team would be gathered together. These are normal times when pieces are introduced, adequate training is done, role playing, et cetera. So I understand him making that a

priority and trying to get that accomplished on that timing.
Q. Now, I think you testified earlier that as of 2012, the FDA had not approved any abuse deterrence claims with respect to reformulated Opana ER, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Yes.
BY MS. SCULLION:
Q. And that remained true throughout the time that you were with Endo, right? Endo asked FDA a few different times to approve ADF claims for reformulated Opana ER, and those were never approved, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I'm only aware of one submission asking for a label change, and that was not approved.
BY MS. SCULLION:
Q. Okay. So throughout the time that you were with Endo, there was never an approved claim for abuse deterrence with respect to the reformulated Opana ER, correct?
MR. LIMBACHER: Asked and

answered.
THE WITNESS: That is correct.
BY MS. SCULLION:
Q. Okay. But Endo did, in fact, position reformulated Opana ER as abuse deterrent, nonetheless, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: No, that's not correct at all.
MS. SCULLION: Can we have E1501 and E1498.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 32.)
BY MS. SCULLION:
Q. I'll hand you what's been marked as Exhibit Number 32.
And Exhibit Number 32 is Bates stamped END00095867, and we've marked it E1501.
And, Mr. Lortie, do you see that Exhibit 32 is a series of e-mails referencing OER pharmacy market research revised report?
A. I see that at the top. I'm just going to, if it's okay, take a moment to look

through the e-mails here.
Q. Yeah.
A. (Witness reviews document.)
Okay. Thank you. I've taken a look.
Q. Sure. Do you recognize Exhibit 32 as a series of e-mails about OER pharmacy market research revised report?
A. The subject line actually changes a few times, but, originally, it's revised report, and then it's OER pharmacy market research revised report, and then it's -- apparently that's forwarded on.
Q. Okay. And what's discussed in these e-mails in part is understanding how payers' treatment of reformulated Opana ER could, among other things, impact the extent to which pharmacists would -- sorry -- the way that pharmacists would treat prescriptions for Opana ER, correct? That's one of the topics?
MR. LIMBACHER: Object to form.
THE WITNESS: No. Actually, I don't agree with that. It does speak to payer policy and how they viewed Opana

ER versus the generic. Pharmacists tend to follow what payers make them do. It's usually directly adjudicated.
BY MS. SCULLION:
Q. Okay. But that's -- I'm sorry, that's exactly what I was trying to get at.
A. The pharmacist usually has very little latitude in those cases.
Q. Okay. And if you'll turn to page 1501.2, top of the page, just looking at an e-mail from Kevin O'Brien to you, he is discussing Aetna at the end of his e-mail, right, Aetna as being one of the plans he's looking at, right?
A. He refers to Aetna as his last sentence, yes.
Q. Okay. And then going to your response to that e-mail on the first page of E1501, you're asking, "Is there anything we can do at Aetna to change their view? The cost of abuse to them and the potential mitigation of that cost should be a compelling story. How can we put it together?"
So you're looking to see if

there's a story that can be put together and presented to Aetna about the relationship between the cost of abuse and the potential to mitigate that through its treatment of reformulated Opana ER, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: Yeah, that's what it's written here. I don't recall the exchange specifically, but that's what the e-mail says.
BY MS. SCULLION:
Q. Okay. And then in response at the top of this same page, Mr. O'Brien writes to you, "We are working in 2 directions," and he explains the work there in points 1 and 2.
And then he goes on to state, "In all cases the customers know the products are not interchangeable and will not force a switch," and that's referring to the reformulated version of Opana ER and generic versions of oxymorphone that were on the market at that time, correct, the interchangeability?
MR. LIMBACHER: Object to form.
THE WITNESS: I believe so, yes.

BY MS. SCULLION:
Q. Okay. And then he states or discusses "The proactive presentations on Intac and abuse since November 1st have been helpful yet the accounts direction and actions has varied."
Had Endo been making proactive presentations to payers in -- from November 2012 through January 2013 discussing the relationship of INTAC and abuse?
MR. LIMBACHER: Objection, form and foundation.
THE WITNESS: I don't recall that being the case, no.
BY MS. SCULLION:
Q. That's what he's referring to, though, is presentations that were made to the payers about INTAC and abuse, right?
MR. LIMBACHER: Objection, foundation.
THE WITNESS: Yeah, that's what's written in Kevin's e-mail, but I don't recall the connection of one to the other.

BY MS. SCULLION:
Q. Okay. Mr. O'Brien was the senior director for reimbursement strategy and operations, managed markets at the time of the e-mail, correct? That's what's stated in his signature block?
A. Yes.
Q. He was a trusted Endo employee in that regard?
A. I suppose so, yes.
Q. You wouldn't expect him to misrepresent an e-mail to you and other senior leadership the nature of the presentations that were being made to the payers, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: It's possible he misinterpreted it, though, so, again, I don't recall the specifics of the presentations that he's referring to, sitting here today.
BY MS. SCULLION:
Q. Well, his discussion of the presentations, in fact, parallels your suggestion about putting together a story to

Aetna relating the cost of abuse and the potential mitigation of that cost in a story to be pitched to them in connection with reformulated Opana ER, correct?
MR. LIMBACHER: Object to form, misstates the evidence.
THE WITNESS: Yeah, again, I don't recall the e-mail exchange or any specific. I do recall, of course, as it's outlined in here that the payers generally did not view the products as interchangeable because the FDA did not view the products as interchangeable. Beyond that, I don't recall the specific presentations. If you've got something you want me to look at, I can do that.
BY MS. SCULLION:
Q. Your e-mail doesn't talk about pitching on the question of interchangeability. Your e-mail talks about pitching them on a story about the cost of abuse and the potential to mitigate that cost, right?
MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: Yeah, again, I'm saying that I don't recall the exchange, and I don't recall the presentations.
BY MS. SCULLION:
Q. Now, you're aware personally that providers did view Opana ER reformulated version as crush resistant, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: To the extent that anyone had that impression, it was not as a result of promotion, because we were not allowed to promote that.
BY MS. SCULLION:
Q. You were not allowed to promote that way, right?
A. We were not allowed to connect crush resistance and abuse potential -- or lack of abuse potential, as we've already established.
Q. I hand you what I marked as Exhibit -- I think it's 33, right?
A. Thirty-three, yes.
(Document marked for identification as Endo-Lortie Deposition

Exhibit No. 33.)
BY MS. SCULLION:
Q. Yeah, Exhibit 33, a document Bates stamped END00465847, and we've labeled it E1498 in the top right-hand corner.
Do you have Exhibit 33?
A. Yes.
Q. And Exhibit 33, if you'll turn to the second page, starts with an e-mail from Diana Frank to you discussing a doctor who visited the GRT booth at pain week.
GRT is that the Grunenthal booth?
MR. LIMBACHER: Take your time and review the document.
THE WITNESS: I'm not sure. It could be. I would draw that conclusion, but I'm not precisely sure about that.
BY MS. SCULLION:
Q. GRT was often used to reference Grunenthal in your time at Endo, correct?
A. That's how I would read this, yes.
Q. Okay. And pain week, what was pain week?

A. I don't specifically recall. I think perhaps it was one of the pain conven -- pain oriented conventions, medical meetings.
Q. Okay. And what Ms. Frank is relaying to you is the doctor had said "he would not prescribe generic oxymorphone because he did not believe that it was the right thing for his patients (because it was not crush resistant)."
Do you see that?
A. Just for clarification, it's Frank Diana as opposed to Diana Frank.
Q. Thank you. I'm so sorry.
A. He was our head of formulation.
Q. Frank Diana very different. It's signed Frank, I see.
A. Yes.
Q. And Mr. Diana --
A. Doctor, in fact.
Q. Dr. Diana is saying to you this doctor viewed generic oxymorphone as inferior because it was not crush resistant, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: That's what's stated here, yes. That was his --

apparently, that was his belief.
BY MS. SCULLION:
Q. And this distinction between generic oxymorphone and reformulated Opana ER based on crush resistance, this was a message that Endo itself again sought to cultivate correct?
MR. LIMBACHER: Object to form, misstates the evidence.
THE WITNESS: No, I'm sorry. I'm not going to agree to that. We have no idea how he drew that conclusion. He's just approaching one of our rep -- one of our company employees and mentioning his frustration because he has been forced to prescribe by the national account, the payer, one product over the one he would like to prescribe. That was not in any way an uncommon circumstance, by the way. Payer policies drive prescribing, and physicians aren't always happy about it.
BY MS. SCULLION:
Q. Well, you had, in fact, market

research that told you that prescribers were learning about Opana ER reformulated being a crush resistant formulation from Endo sales representatives, you had market research that told you that, right?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't recall seeing that, no.
MS. SCULLION: Can I have Exhibit 1409, E1409.
BY MS. SCULLION:
Q. Let me hand you what has been marked as Exhibit -- sorry, I didn't keep track.
A. Thirty-four.
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 34.)
BY MS. SCULLION:
Q. Thank you, 34, which is Bates stamped ENDO-CHI_LIT-00135664, and we've marked in the upper right-hand corner E1409. If you'll turn to the first page of the PowerPoint, which is E1409.3, this is reporting on "Opana ER Crush-Resistant Formulation Research, Wave 5,

Qualitative Interviews" dated December 13th, 2012, correct?
A. Yes. I'll just take a minute, if it's okay, and look through the deck.
Q. Sure.
A. (Witness reviews document.)
Okay. I've taken a look at most of the pages.
Q. Okay. And Exhibit 34 is reporting on market research that the KJT Group did on behalf of Endo, correct?
A. Apparently, yes.
Q. And KJT Group was a vendor that Endo used regularly to perform market research in this time frame, summer of 2012?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't know that to be the case. It's not a name I recognize.
BY MS. SCULLION:
Q. Okay. I think we've seen it a few times.
In any event, they performed this research for Endo.

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And if you go to page E1409.9, the research is producing what's described here as the "Evidence." In first bullet point, "Most prescribers learned of the crush-resistant formulation from an Endo sales representative," correct? That's what it says?

A. Yeah, it is. I'm noting, though, there's a footnote to that, which kind of confuses me a little bit. It says "based on quantitative tracking research," so I'm not sure of what the vendor is using as evidence. I think what they're saying is there's a correlation that -- or at least there's quantitative evidence that these prescribers were called on by representative, unless there's something I'm missing, but I'm not sure how they're drawing that conclusion. I'm not saying it's inaccurate, but it's interesting to note that they've got this footnote here. So I'm a little confused by that.

Q. So based on --

MR. LIMBACHER: I apologize for interrupting, but my real time is not working. I don't know if I did

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something or what, I apologize, but I need a little technical help.

THE VIDEOGRAPHER: Off the record, 5:35.

(Pause.)

THE VIDEOGRAPHER: It is 5:36. We are back on the record.

BY MS. SCULLION:

Q. Back on the record. Still on page E1409.9, Mr. Lortie. The report does say that "Based on the quantitative tracking research, most prescribers learned of the crush-resistant formulation from an Endo sales representative," correct; that's what it says?

A. Yeah, again, as we just described, there's this kind of confusing footnote that says based on quantitative tracking research, I'm really not sure what that means.

Q. But it is -- whatever that research is, this is what the findings are based on?

A. It's the conclusion that the market research company is presenting.

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Q. Right. And two more bullet points down, the conclusion is also that "A majority of prescribers have heard all of Opana ER's crush-resistant formulation messages," correct; that's what it reports here?

A. That is what it's -- that's what's written in the box, yes.

Q. Okay. If you go to the next page, E1409.10, again, in the evidence box, last bullet point, the evidence recited here, again, based on quantitative tracking research -- actually, I take that back. This one does not say based on quantitative tracking research. The last piece of evidence cited in that box is "The new 'crush resistance' was seen as a benefit (lower abuse potential), raising prescriber comfort level with Opana ER, and potentially leading to increased prescribing in the future."

Did I read that correctly?

A. You read that correctly.

Q. And so this research report was telling Endo that prescribers were getting most -- getting nearly all their information

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from Endo sales representatives were seeing crush resistance as a benefit because of their understanding that that indicated a lower abuse potential for the product, correct?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: No, I actually can't agree with that. It says most prescribers learned of the crush-resistant formulation --

BY MS. SCULLION:

Q. Thank you.

A. -- from a representative. It doesn't suggest, as you had put, that they got most of their information from a representative.

Q. You're right. I did misstate that. They learned of it from the sales representative.

A. So they were made aware that this new formulation existed, that's my conclusion that I draw from that statement.

Q. Okay. And what they've become aware of is that the new crush resistance was seen as a benefit because, in their

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understanding, it created a lower abuse potential for the product, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: And, again, I don't think I can draw that same conclusion.

What I draw from the two pieces of information that you're asking me to review is that they were made aware of the new formulation by representative and that their interpretation of crush resistance, according to this, was that there was a benefit (lower abuse potential), but, you know, my experience is the physicians get their information from lots of different places, lots of different sources.

So I don't think you can necessarily draw the direct correlation to any sales representative messaging and what a given physician might conclude. As we've said before, our representatives were not allowed to promote any benefit other than designed to be crush resistant, which explained

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the difference between the new pill and the old pill.

BY MS. SCULLION:

Q. What was the relevance, why was the message designed to be crush resistant a relevant message to physicians?

A. We heard from physicians that it was important that they understood what was different between the two formulations, and they knew that we were attempting to, in our own way, mitigate a potential route of abuse. That was well publicized, and, frankly, they applauded that.

What they did not hear from our representatives, though, was the nexus between that fact and any proven ability to mitigate abuse because we had not proven that. Our reps were trained not to speak that way and all of our material had a qualifier that made that very, very clear.

Q. And you say it was well publicized that Endo was seeking to mitigate a potential route of abuse.

Endo publicized that in part

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through the press release that it issued when it sued the FDA -- sorry, when it filed a citizen's petition with the FDA, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: I don't recall the specific public relations or the specific press release, but, you know, this was a topic that was spoken about in the media during the period of time this was all occurring.

BY MS. SCULLION:

Q. Right, and the topic spoke about in the media was that Endo contended that its new reformulation of Opana ER, in fact, did provide a safety advantage with respect to potential routes of abuse for oxymorphone, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: The general tone of the coverage was recognized that Endo was trying to present a new formulation of the product that might mitigate abuse but that also it was in conversations with the FDA and creating new clinical

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data before it was able to do that. So there were media reports, et cetera, and if you've got a press release there, I don't recall specifically the press release, but we did take certain actions, as you mentioned, with regards to suing the FDA and others.

MS. SCULLION: So do we have the press release?

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 35.)

BY MS. SCULLION:

Q. Hand you what's been marked as Exhibit 35.

And Exhibit 35 is a copy of a -- publicly available on Endo's website -- a copy of a November 30th, 2012 press release entailed "Endo Health Solutions Sues FDA to Protect Consumers from Non-Tamper Resistant Oxymorphone."

Did I read that correctly?

A. Yes, that's the headline.

Q. And the subheadline in the press

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release says, "Surveillance data show dramatic decrease in abuse rates of reformulated Opana ER designed to be crush-resistant when compared to non-tamper resistant formulation."

Did I read that correctly?

A. You did.

Q. So Endo is highlighting in this press release surveillance data that it says showed a dramatic decrease for abuse rates for the reformulated Opana ER with the intent to be -- to indicate that there's a lower rate of abuse for reformulated Opana ER as compared to generic oxymorphone, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Or the non-tamper resistant formulation, specifically.

BY MS. SCULLION:

Q. And the non-tamper resistant formulations on the market as of November 2012 were the generic oxymorphone manufactured and sold by entities other than Endo, right?

A. Yes. By November the original branded product was, to a great extent, out of the distribution channel by that point.

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Q. Now, was Endo allowed to make a claim with respect to the reformulated version of Opana ER that it was tamper resistant?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: No, I don't believe so.

BY MS. SCULLION:

Q. Okay. But throughout this press release, Endo is specifically contrasting reformulated Opana ER to non-tamper resistant generic oxymorphone, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: It is using non-tamper resistant formulations, yes, to describe the other formulation.

BY MS. SCULLION:

Q. And it's contrasting those non-tamper resistant formulations to the reformulated version of Opana ER, correct?

A. It's describing the reformulated version specifically is designed to be crush resistant, that's how it's referring to the new product, and it's referring to the old product

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or the generic, in this case, as non-tamper resistant formulation.

Q. Well, in fact, in the press release, Endo specifically refers to reformulated Opana ER as crush resistant, if you look at the bullet points one, two -- the four bullet points in the middle of the first page.

Do you see that?

A. So the fourth bullet point I see. What's your question?

Q. I apologize. There's four bullet points is what I meant to say.

Do you see that?

A. In the center?

Q. Yes. And in the second bullet point --

A. I'm sorry. The question was?

Q. Yeah, Endo refers to the requirement that any abbreviated new drug applications referencing Opana ER contain data and information demonstrating that the proposed ANDA product is similarly crush-resistant as the reformulated Opana ER designed to be crush-resistant.

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Did I read that correctly?

A. Yes, and just for clarity, the four bullet points are explained as specifically what is asked for in the citizen's petition that Endo has in front of the agency at this time.

Q. Right.

And in describing that citizen's petition, Endo is stating that any generic version of Opana ER should have to be demonstrated to be similarly crush resistant to reformulated Opana ER, right?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: Yeah. Again, what they're ask -- what they're stating here is that the citizen's petition, among other requests, is asking that the FDA require that any ANDA that references Opana ER contain data and information that demonstrates that it has the same physical properties. That's the way I would read that.

BY MS. SCULLION:

Q. And the physical property,

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though, stated here in this press release is crush resistant, didn't just say physical properties?

A. Or resistant -- resistance to crushing.

Q. Right. And that's the physical property that Endo is highlighting with respect to Opana ER, correct?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: Well, again, I think I've stated that before. What it says is they're asking that any ANDA that references Opana ER has to have the same evidence suggesting the same physical properties to confer similar resistance to crushing forces.

BY MS. SCULLION:

Q. Right. So, I mean -- and then the next bullet point, again, Endo says its citizen's petition also calls for "the classification of crush-resistant technologies, such as the reformulated crush-resistant Opana ER."

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So it's ascribe -- Endo is ascribing reformulated Opana ER here as crush resistant, did not say designed to be crush resistant, crush resistant; that's what it says, right?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: That is what it says, yes.

BY MS. SCULLION:

Q. Right.

Endo wasn't asking that the ANDAs for generic versions of Opana ER really had to show that they were designed to be crush resistant. It said they had to be crush resistant; that's what it's asking for, right?

MR. LIMBACHER: Object to form, misstates the evidence.

THE WITNESS: It was asking the FDA that if any ANDA for a generic referenced Opana ER, the new form that was designed to be crush resistant, that those ANDAs should also have to show the same physical resistance to crushing.

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BY MS. SCULLION:

Q. And Endo was aware when it put out this press release, obviously that is a public press release, correct?

A. It's a press release, yes.

Q. Right, expected that press release to get then picked up by the media, correct?

A. Yes. I mean, part of this is a requirement when a publicly traded entity is doing something as significant as suing the FDA, you have to make a press release about it.

Q. And Endo expected this press release to get some attention, correct?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: Well, I don't know to what extent there was a desired goal of attention, but it was required, given the importance of the action that was being reported, that we reported it to the public.

BY MS. SCULLION:

Q. And Endo expected that this press

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release, for example, could be conveyed through media to doctors that its sales reps were calling on, those could be among the audience to whom this press release could be conveyed in the media?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I think that physicians could be exposed to media, but the press release did not have the goal of reaching physicians.

In other words, this was not a veiled attempt at promoting to physicians. This was a public -- a press release on an important legal action being taken by a pharmaceutical manufacturer against the FDA.

BY MS. SCULLION:

Q. Now, you said in -- that in its promotional materials, you're very clear that Endo was careful to say designed to be crush resistant and have that caveat that -- data to show any impact on abuse liability did not exist, had that caveat in its promotional

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materials, correct?
A. Correct.
Q. Didn't have that caveat in this press release, right?
A. It does actually. If you look at the -- sort of the second paragraph from the bottom, it's speaks explicitly about the abuse potential so, you know -- and oftentimes, if not always, these were also distributed with a copy of the prescribing information.
Q. Right. So it's just --
A. So it's not a piece of promotion and, therefore, the juxtaposition of that next to the discussion is not required, but the abuse potential is clearly pointed out here.
Q. So you say this is not a piece of promotion, so the press release then didn't have to go through MARC review, right?
A. A press release would have been MARC reviewed, yes.
Q. So it did go through MARC review?
A. It went through a version of MARC review, but, again, because it's not a piece of promotion, press releases and other public

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statements had a different category of review, but the same medical, legal, regulatory actually often at a more senior level.
Q. Do you know if Endo tracked how many times this press release was picked up?
A. I do not know.
MS. SCULLION: And then can we have E959, 1494, 1483.
BY MS. SCULLION:
Q. Now, the other way that Endo -- another way that Endo got out the message that the reformulated version of Opana ER was crush resistant was through a formulary -- I'm sorry -- compendia submissions, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: No, that's not correct.
BY MS. SCULLION:
Q. Do you recall that Endo did make submissions with respect to reformulated Opana ER to various compendia?
A. Yes, that's normal practice. The compendia are independent, third party groups who offer opinions that are used by the payers

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and health insurers.
Q. Right.
They're used by various components of the medical community, those opinions, correct?
A. Specifically payers, health insurers and the like.
Q. And you were personally involved in Endo's efforts to have Opana ER reformulated version listed as a crush-resistant dosage form by the compendia, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: No, that's not correct.
BY MS. SCULLION:
Q. Were you involved in Endo's submissions to the compendia for Opana ER reformulated?
A. I don't recall being directly involved, no.
Q. Okay.
MS. SCULLION: Go to E959.
(Document marked for identification as Endo-Lortie Deposition

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Exhibit No. 36.)
BY MS. SCULLION:
Q. I've handed you what's been marked as Exhibit 36. I'll look at the Bates Number in one second.
MR. LIMBACHER: Take your time and review the document.
(Witness reviews document.)
BY MS. SCULLION:
Q. Have you had a chance to review the exhibit?
A. I have. Just I'm noting page 2, 959.2 is blank. Is that intentionally blank?
Q. Yes.
A. I just wanted to make sure I'm not missing an e-mail or something.
Q. No, no, you're not.
And if you look at the exhibit and turn to page E959.3, it's labeled "Compendia status update" dated December 2012, correct?
A. It is, yes.
Q. And then the next page, E959.4, is reporting that "All 3 Data Compendia have uniquely classified Opana ER with INTAC

technology based on the dosage form of Crush Resistant," correct?

A. Yes.

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. You were aware at the time that all three data compendia had, in fact, classified Opana ER based on dosage form crush resistant?

A. I was aware once those conclusion had been drawn that the three compendia had independently taken those positions, yes.

Q. Okay.

A. In other words, after that conclusion had been drawn.

Q. And were you aware that Endo had been seeking such dosage form classification for reformulated Opana ER?

A. Not specifically seeking anything. You don't seek anything with the compendia. You submit -- it's usually a physician-to-physician interaction. You submit clinical data as they request and they draw their own conclusions. It's not a matter of

what you're seeking.

Q. Well, with respect to the compendia, Endo did have to choose to submit data to the compendia, correct?

A. I'm not aware of any time a new product would not have had such a submission. The payers require that. It's part of their information to make determinations on products, so it's just very common.

Q. Okay. And do you recall that at least with respect to -- strike that.

Let's just go to the next page, E959.5, and it's stated at the top here "Data Compendia decisions have tremendous downstream effects on retail, MCO, providers, and patients."

Do you see that?

A. Yes, that's the title on the slide 3.

Q. Okay. And among the downstream effects of compendia decisions identified in this document is on the right-hand side, you see under "Patient and Provider, social implications."

You see that?

A. Yes.

Q. And social implications were important with respect to an opioid like Opana ER reformulated version, correct, because of the stigma sometimes associated with opioids?

MR. LIMBACHER: Object to form.

THE WITNESS: I actually don't know what's meant here by social implications.

BY MS. SCULLION:

Q. Okay. And it also speaks in this slide to the downstream effects on "provider intent when prescribing," correct?

A. I'm sorry, I didn't understand the question.

Q. That's what it also speaks to "provider intent when prescribing" as being one of the downstream effects of compendia decisions?

A. Yes. Again, I'm not quite sure what's meant by that, but that's in that banner of patient and provider.

I also note that on the left,

compendia is described as clinical discretion and nonbiased clinical position or highlighted, that's why the managed care organizations depend on the views of the compendia. And that point actually is represented in the middle, that the managed care organizations rely on these independent compendias as safeguard for unbiased data and clinical information.

Q. Endo engaged, in fact, an outside vendor to oversee this compendia submission with respect to reformulated version of Opana ER, correct?

A. I don't specifically recall. I wasn't part of the -- that part of the development. It was in a group a few layers away from me, so I don't recall specifically the mechanics in this case.

Q. You don't recall that Endo engaged an entity called Two Labs to act as its agent in presenting the new NDCs for Opana ER to three major data warehouses?

A. That's correct, I do not recall that specifically.

Q. Okay. You don't dispute that,

though?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't recall it.
I think that was your question.
BY MS. SCULLION:
Q. And, as I understand it, the way that the compendia work is they -- by creating a new dosage form, crush resistant, the pharmacies or payers that subscribe to that compendia would be getting information labeling Opana ER, the reformulated version, as crush resistant, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: No, I don't think that's accurate.
BY MS. SCULLION:
Q. If you go to the next page, E959.6, this says it's an example of Opana ER 5-milligram unique GPI and dosage form from Medispan.
Do you see that?
A. Yes.
Q. And Medispan was one of the compendia?

A. That's I believe true, yes.
Q. And the product name that Medispan would use for Opana ER reformulated version was Opana ER (crush resistant); that was the name that was going to appear in the Medispan compendia, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I don't recall specifically, but that appears to be what's represented here.
BY MS. SCULLION:
Q. If you go to the next page E959.7, this recaps the "Compendia process-to-date" as of December 2012.
Do you see that?
A. Yeah, I don't see December 2012.
Q. December 2012 is the date of the document.
A. It's the date of the document, but, yes.
Q. It says "Compendia process-to-date"?
A. It says quarter 1, 2, 3, 4, but it doesn't say which year.

Q. The document is dated December of 2012, right?
A. The title is 2012, yes.
Q. Okay. And you see on the left-hand side it says "Identified risk and engaged Two Labs."
Do you see that?
A. I do.
Q. Okay. So and then we see that TL, which is Two Labs presented all the info to the compendia, that's near the end of Q1, correct?
MR. LIMBACHER: Object to form.
THE WITNESS: I see that.
BY MS. SCULLION:
Q. Right.
And then we see in Q2, "Gold Standard and Medispan created unique dosage form/identifier for crush resistant."
So those two compendia had taken the step of creating the new crush-resistant dosage form, right?
A. Yes.
Q. And you see there's at the bottom

a discussion of a meeting with the VP of FDB.
FDB was another compendia, right?
A. Yes, I believe so.
Q. It says a meeting with FDB, and on the top half of the timeline you see in Q3 a meeting with editorial director of FDB.
Do you see that?
A. Yes.
Q. Okay.
A. That was following the initial -- it looks like an initial meeting where the company was informed that, at least in their opinion, FDB had a very stringent clinical review process with minimal engagement from manufacturers.
Q. Right. But that engagement here included at least a meeting with the VP and then a meeting with the editorial director, correct?
A. Yes.
Q. And then a -- it says a presentation of "more robust clinical data and call to action to FDB."
A. Yes, I see that.
Q. Right. So Endo not only had two

meetings with FDB, but it went back and presented more clinical data and made a call to action to FDB to make a decision about a crush-resistant dosage form, correct?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I don't think I can draw that conclusion from this. It doesn't say who was presenting each one of these times.

BY MS. SCULLION:

Q. Well, it's describing the compendia process by Endo, right? Was anyone else presenting other than Endo's agent?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: I don't know. I mean, in some of these cases, advisors would present. In some of the cases, many cases, the compendia would call on their own independent advisors. It's really important to point out that the very business of these compendia is about being independent. We've seen

themes of that throughout all the documents you've shown me, they're independent third parties that don't rely on manufacturers, that draw their own conclusions and upon which the managed care organizations depend.

(Document marked for identification as Endo-Lortie Deposition Exhibit No. 37.)

BY MS. SCULLION:

Q. Let me hand you what's been marked as Exhibit Number 37.

And Exhibit 37 is Bates stamped END00121820, and we've marked it E1494 at the top.

And directing your attention to middle of page E1494.2, do you see the e-mail from Marv Kelly to Jason Jones on January 13th, 2013 when she says, Jason, "any way to influence First Data Bank to accelerate their update?"

A. Yes, I see that communication.

Q. And Jason responds at the top, "I believe FDB will be making the move this week. We will follow up with compendia listings as

well as our trade customers this week - now that Impax is on the market."

Do you see that?

A. Yes, I do.

Q. And then on the first page of the exhibit, E1494.1, you see an e-mail from Simon Lemmy to Jason Jones and others on January 13th?

A. Yes.

Q. And he actually addresses the e-mail to Marv, Marv Kelly, correct?

A. Looks like to Jason Jones and Marv Kelly.

Q. But then the body of the e-mail, he's addressing it to Marv.

Do you see that?

A. I do, yes.

Q. And he says, "We were in contact with FBD last week, through our consultant, and they have committed to updating their systems next week and communicating to their customers."

So this is another example of Endo, through its consultant, was in contact with FBD, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Yeah, apparently asking for an update on their process and timing.

BY MS. SCULLION:

Q. Right.

So now you were copied on Mr. Lemmy's e-mail, correct?

A. The January 13th e-mail?

Q. Yes.

A. Yes, I was.

Q. And then you respond, "Simon and team - thanks for the diligence on this mission-critical work."

So you regarded the compendia listings for reformulated version of Opana ER as mission critical to Endo, correct?

MR. LIMBACHER: Object to form.

THE WITNESS: Yeah, it was very important.

BY MS. SCULLION:

Q. But it was mission critical important, right?

MR. LIMBACHER: Object to form.

THE WITNESS: That's the language

I used.
BY MS. SCULLION:
Q. And why was that?
A. Well, the managed care organizations require input from the compendia before they can load that information into their system, so just from the very basic requirement that a new product doesn't get reimbursed until there's a compendia load in of data in the compendia's view, it's mission critical. So, you know, I'm referring to that importance and also thanking the team for their diligence in bringing about the action, bringing about the activity and making sure that the compendia did their work on a timely basis and helping to manage that process.
Q. This wasn't just about getting the compendias to list the reformulated version of Opana ER, it was about getting them to create a new dosage form listing it as crush resistant, right?
MR. LIMBACHER: Object to form.
THE WITNESS: We had no ability to influence that. We were pleased that

they recognized that the products were different and that they reported it that way, but we had no ability to influence that, other than supplying them with our clinical data and the other physician-to-physician communications.
MS. SCULLION: Take a quick break. We have the document with us before. Let's go back to that.
THE VIDEOGRAPHER: The time is 6:10. We are going off the record.
(Brief recess.)
(Document marked for identification as Endo-Lortie Deposition Exhibit No. 38.)
THE VIDEOGRAPHER: We are back on the record at 6:22.
BY MS. SCULLION:
Q. Mr. Lortie, we've handed you off the record and provided to counsel a copy of Exhibit Number 38, which is Bates stamped ENDO-CHI_LIT-00467546, and we've Bates stamped it -- or, sorry, stamped the top right-hand corner E119.

Do you recognize Exhibit 38 or the attachment, I should say, to the e-mail, the cover of Exhibit 38 as a copy of the August 2012 "Opana ER Strategic Platform"?
A. I don't necessarily recognize it. I have not reviewed this document in preparation, but I see that the title is "Opana ER Strategic Platform," as you point out, August of 2012.
Q. And just so we're -- so I'm extra clear, I am asking these questions in your personal capacity at the moment.
A. Okay, thank you.
Q. So if you look -- let's start with the first page of the exhibit, which is an e-mail from Kristin Vitanza to you in January of 2013, in which she is transmitting to you the final document for the Opana ER strategy plan?
Do you see that?
A. Final ER strategic platform as opposed to strategy plan.
Q. I apologize. Her words were "the final document the Opana ER Strategy Plan."
A. Which is interesting.

Q. But, you're right, it is, in fact, a strategic platform, correct?
A. Yes, now the extent to which -- I'm not sure -- that's why I was flipping through. I don't recall specifically what strategic platform was at that point, but I was trying to educate myself on that.
Q. Well, so that was the question I had for you is looking at Exhibit 38, do you recall a strategic platform being prepared for Opana ER in August 2012?
A. I don't. I can refresh my recollection by looking at it, but I don't recognize it specifically, no.
Q. So you've looked through it and it doesn't refresh your recollection?
A. I began that process and then we went back on the record.
Q. Well, let me ask you, let you look through the document, do you recall using a strategic platform for any products while at Endo?
A. No. Actually, the term and the format of this doesn't jump out at me as being

familiar. But, again, I saw many documents during my time there, and this is quite some time ago.

Q. Okay. If you want to just flip quickly through the document and see if it refreshes your recollection, and I can point you to some specific pages.

A. Okay. Give me just a moment. It's quite a comprehensive document.

(Witness reviews document.)

Why don't you point me where we're going to go.

Q. Sure, that might be good --

A. Because, otherwise, I might be flipping through pages --

Q. I think that would be easier.

A. -- that aren't helpful.

Q. Well, let me just orient you. If you look to page E119.6 and 119.7 looks to be an explanation of the overview of the strategic platform format, at least, with copies I should say.

You see it discusses that the strategic platform dossier is an internal

resource tool that outlines evidence-based foundations/beliefs, provides strategic foundation and referenced evidence that support how we communicate about a treatment/disease and guides coordinated activities throughout a product's lifecycle.

Do you see that?

A. Yes, I do.

Q. And if you go to page E119.18, which is entitled "Summary of Data Gaps," start with that first page.

A. 118 is the first page?

Q. Correct, of the Summary of Data Gaps.

A. I have that open.

Q. This appears to be, correct, a statement of aspirational statements about in this case Opana ER and whether there is data as of the date of this strategic platform to support that aspiration or whether, as noted in the top row there, data is needed; is that your understanding of what this is conveying?

MR. LIMBACHER: Object to form.

THE WITNESS: I'm reading it in

real time right now. I mean, I honestly don't recall how this was used, but, you know, given the helpful slide that tried to explain the purpose of the document, so what I read here is that the data needed column indicates areas for potential investment in producing additional data. Whether or not that means there's zero data now and there's data desired in the future or there's need to complete the data set, it's not clear.

BY MS. SCULLION:

Q. Okay. This is a summary of -- it says Summary of Data Gaps, you see that?

A. Yes.

Q. If you go to -- let's go to page E119.51?

A. 51, okay.

Q. Just to understand what is meant here by data gap, you see on the right-hand side, there are colored radio buttons on this page? You see green and red and on some of the following pages, you'll see also yellow?

A. I just got to 51, so let me look at it.

Q. Sure.

A. Yes, I think I see -- I think I understand the reference here.

Q. Right. And then there's a key at the bottom of this page which explains what is meant by those radio buttons. So that green equals no gap for that particular item; yellow being a study is planned or in progress to fill the gap, correct?

A. Yes.

Q. And red indicates a gap exists and no study is currently planned, right?

A. That's what the legend explains. That's how the legend explains the colors, yes.

Q. Okay. Let's keep paging ahead, so for example, to page E119.53.

Do you see under the column that's labeled "Data/Gap," the second row describes "Chart review to demonstrate improved functioning and sleep, and good tolerability profile with Opana ER."

Do you see that?

A. Yes, I do.
Q. And then in response to whether there is, in fact, a data gap for that item, there's a red radio button.
Do you see that?
A. Yes, I do.
Q. And is it correct that then that means that there was no data to support -- sorry, strike that.
Does that red radio button mean that there was, in fact, no chart review at the time of this strategic platform and no study currently planned, in this case a chart review?
MR. LIMBACHER: Object to form and foundation.
THE WITNESS: Yes, with that specific point that you added. It speaks to chart review, not lack of data completely.
BY MS. SCULLION:
Q. Correct. It's stating what data is missing, correct?
A. It's stating in this case that a chart review to demonstrate these attributes has

not been conducted, and, apparently, there's no plan to conduct that either.
Q. Okay.
A. Currently, as of this -- as of the date of the production.
Q. Okay. And that would be true with respect to each of the then red radio buttons throughout this gap analysis, that the red radio button is indicating that the specific data indicated in the data gap column does not exist, and no study is currently planned to fill that gap?
A. That's what the legend says. Red equals gap exists with no study currently planned.
Q. Okay. Having looked at Exhibit 38 a little bit more, does this refresh your recollection at all around the strategic platform for Opana ER?
A. Unfortunately not. I literally don't recall ever seeing this. It's an extraordinarily comprehensive document, and I'm surprised I don't, so I don't -- I mean, Kristin sent it to me, so it certainly was e-mailed to

me, but it was six years ago, so perhaps that's the reason.
Q. Even putting aside the document, do you recall, let's say, in the January 2013 time frame any discussion about looking at what data or studies may be needed to extend the lifecycle for Opana ER?
MR. LIMBACHER: Object to form.
THE WITNESS: Not specifically, not without something to react to, I don't.
BY MS. SCULLION:
Q. Was lifecycle management one aspect of your responsibilities in January 2013, lifecycle management for Opana ER?
A. Lifecycle management was always a cross-functional team or the responsibility for cross-functional team that included commercial teams, so there would have been people who reported up through my chain that were part of that but also people from medical and regulatory, et cetera, the other, you know, the classic cross-functional teams in a pharma world, so it what was a shared accountability.

Q. And as part of that shared accountability, do you recall at any point in time after the launch of reformulated Opana ER consideration of potential ways to extend the lifecycle of the product?
A. Of the reformulated product?
Q. Correct.
A. To extend the lifecycle, not sitting here right now, I don't recall any specifics related to that.
Q. Okay. Was the success of the citizen's petition Endo had filed against the FDA to require -- strike that -- to have the FDA find that Endo had withdrawn original Opana ER for reasons of safety, was that something that Endo understood, if successful, would extend the exclusivity for Opana ER through 2029?
MR. LIMBACHER: Object to form.
THE WITNESS: Not necessarily. Again, there were intellectual property -- there was intellectual property litigation ongoing throughout that period that actually the company prevailed in. So the citizen's petition

wasn't about extending exclusivity per se, it was about asking the agency to find that the old product had been removed for reasons of safety, as you pointed out.

BY MS. SCULLION:

Q. But if Endo had been successful in that citizen's petition, that is to remove the original formulation of Opana ER NDA, then the potential competitors would have to go through Paragraph IV and patent challenge process with respect to the reformulated version of Opana ER, correct?

MR. LIMBACHER: Object to form and foundation.

THE WITNESS: Yeah, I believe that's generally correct.

BY MS. SCULLION:

Q. Okay. And Endo believed that if the potential competitors were forced to do that, that could potentially result in ongoing exclusivity for reformulated Opana ER through 2029, correct?

MR. LIMBACHER: Object to form

and foundation.

THE WITNESS: You know, again, as I just mentioned, there was ongoing patent litigation really to address those topics, which the company ended up prevailing in. So the exclusivity period, as it was determined, was actually independent of the -- of any changes to the product.

BY MS. SCULLION:

Q. We've looked at Exhibit 38. I take it based on your testimony that you don't recall the document, and you don't recall discussions around data gaps concerning Opana ER. But you have no reason, though, to dispute the accuracy of the statements in the document as to certain data gaps that it does identify --

MR. LIMBACHER: Object to form.

BY MS. SCULLION:

Q. -- sitting here today?

MR. LIMBACHER: The witness has not had an opportunity to review the entirety of the document.

THE WITNESS: Again, I don't

recall reviewing it. I don't have any reason to dispute it, but I also can't -- can't attest to the validity of any of it because I wasn't the author. I wasn't involved in the development of it.

MS. SCULLION: So we're going to end for today. We have gone past 6:00. We've tried to do, frankly, a good unit, but we're going to end for today and resume the deposition tomorrow at approximately 2:30, if that is convenient to you?

THE WITNESS: Yes, thank you, that will work.

MR. LIMBACHER: I just want to be clear before we all leave here today that it's our position that we should be able to get this deposition completed tomorrow. I would ask that everybody use their best efforts to get it completed tomorrow.

And do you have any expectation as to how much more you have?

MS. SCULLION: I do not, sitting here today, but we can talk tomorrow. I would anticipate that our portion of the deposition would be done tomorrow. I know that counsel from Tennessee is also here, so I suspect he'll have some examination, as you may as well.

MR. LIMBACHER: Understood. Thank you.

THE VIDEOGRAPHER: That concludes today's testimony. The time is 6:38 p.m.

(Witness excused.)

CERTIFICATION

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I, BRIAN LORTIE, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

BRIAN LORTIE DATE

Subscribed and sworn to before me this

_____ day of _____, 2018.

My commission expires:_____

_____

Notary Public